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Filed Pursuant to Rule 424(b)(4)
Registration No. 333-220857

PROSPECTUS

5,333,333 Shares

Common Stock

This is the initial public offering of shares of common stock of Allena Pharmaceuticals, Inc. We are offering 5,333,333 shares of our common stock. Prior to this offering, there has been no public market for our common stock. The initial public offering price per share is 14.00. Our common stock is listed on The Nasdaq Global Select Market under the trading symbol "ALNA."

We are an "emerging growth company" under applicable Securities and Exchange Commission rules and will be subject to reduced public company reporting requirements for this prospectus and future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 12.

	Per Share	Total
Initial public offering price	$14.00	$74,666,662
Underwriting discounts and commissions(1)	$0.98	$5,226,666
Proceeds to us, before expenses	$13.02	$69,439,996

(1) We have agreed to reimburse the underwriters for certain FINRA-related expenses. See "Underwriting" for additional disclosure regarding underwriting discounts, commissions and estimated expenses.

Certain of our existing stockholders who previously indicated an interest in purchasing shares of our common stock in this offering, including certain affiliates of our directors, have agreed to purchase an aggregate of approximately $20 million of shares of our common stock in this offering at the initial public offering price.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 800,000 shares of common stock from us at the initial price to the public less the underwriting discount.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares against payment in New York, New York on November 6, 2017.

Credit Suisse **Jefferies** **Cowen**

Wedbush PacGrow

Prospectus dated November 1, 2017

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We are responsible for the information contained in this prospectus and in any free-writing prospectus we prepare or authorize. We have not, and the underwriters have not, authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the cover page of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

Through and including November 26, 2017 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes thereto and the information set forth under the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case included in this prospectus. Unless the context otherwise requires, we use the terms "Allena," "the Company," "we," "us," "our" and similar designations in this prospectus to refer to Allena Pharmaceuticals, Inc. and its wholly owned subsidiaries.

Overview

We are a late-stage clinical biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders. We are focused on metabolic disorders that result in excess accumulation of certain metabolites, such as oxalate and urate, that can cause kidney stones, damage the kidney, and potentially lead to chronic kidney disease, or CKD, and end-stage renal disease. Our lead product candidate, ALLN-177, is a first-in-class, oral enzyme therapeutic that we are developing for the treatment of hyperoxaluria, a metabolic disorder characterized by markedly elevated urinary oxalate levels and commonly associated with kidney stones, CKD and other serious kidney diseases. There are currently no approved therapies for the treatment of hyperoxaluria. We have conducted a robust clinical development program of ALLN-177, including three Phase 2 clinical trials, and we expect to initiate the first of two planned pivotal Phase 3 clinical trials for ALLN-177 in the first quarter of 2018, with topline data anticipated in the second half of 2019.

Using our proprietary technological approach, we developed ALLN-177, a crystalline formulation of the enzyme oxalate decarboxylase, to specifically degrade oxalate within the GI tract, allowing for its removal from the body through the bowel. This mechanism of action reduces the accumulation of oxalate in the body and therefore limits the burden on the kidney to filter and then excrete it in the urine. The data from our clinical trials and numerous academic studies suggest the potential for GI elimination of oxalate to reduce the chronic disease burden on the kidney and other organ systems.

Oxalate is endogenously produced as an end product of normal cellular metabolism and is also absorbed through a typical diet. Humans lack the innate capacity to digest oxalate and primarily depend on renal excretion to eliminate it from the body. Although oxalate has no identified biological function, it is known to damage the kidney when present in excess amounts, a condition called hyperoxaluria. Hyperoxaluria is characterized by significantly elevated oxalate levels in the urine, or urinary oxalate excretion, due to either overproduction of oxalate by the liver from a genetic defect, called primary hyperoxaluria, or from over absorption of oxalate from the diet, called secondary hyperoxaluria. Secondary hyperoxaluria is further characterized either as enteric, resulting from a chronic and unremediable underlying GI disorder associated with malabsorption, such as bariatric surgery complications or Crohn's disease, which predisposes patients to excess oxalate absorption, or idiopathic, meaning the underlying cause is unknown. Enteric hyperoxaluria is the more severe type of secondary hyperoxaluria. Systemic oxalosis, which typically occurs in patients with primary or severe secondary hyperoxaluria and declining kidney function, refers to the presence of excess oxalate throughout the body, including the blood, bones, joints, eyes and heart.

We estimate there are approximately 200,000 to 250,000 patients in the United States with enteric hyperoxaluria and kidney stones. We plan to target this market initially. We believe that a therapeutic agent that reduces urine oxalate levels in this population could be commercialized into a potential multi-billion dollar U.S. market without any approved therapies at present. Primary hyperoxaluria, an ultra-rare genetic disease, is estimated to affect approximately 1 in 58,000, or approximately 5,000 patients, in the United States. Among

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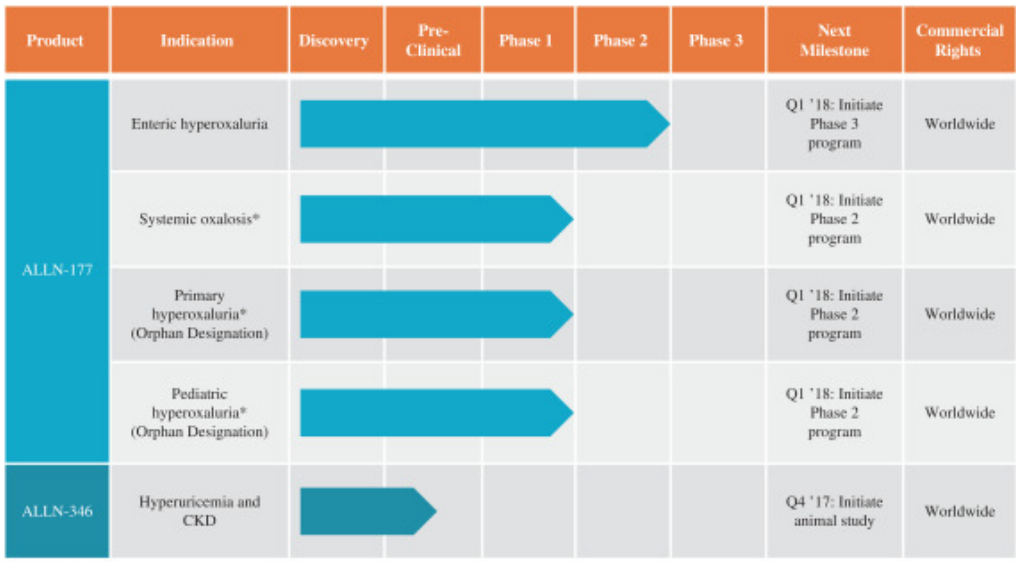
patients with primary hyperoxaluria, about 50 percent will have kidney failure by age 15, and about 80 percent will have kidney failure by age 30. There are no therapies for primary hyperoxaluria approved by the U.S. Food and Drug Administration, or the FDA, and the most severe patients may be treated with a liver and/or kidney transplant. Patients with enteric hyperoxaluria can have levels of urinary oxalate excretion as high as patients with primary hyperoxaluria and a comparable renal burden.

Our Programs

We have developed a pipeline of first-in-class, oral, non-absorbed enzyme therapeutic candidates to treat patients with rare and severe metabolic disorders that affect the kidney. Our lead product candidate, ALLN-177, is an oral enzyme therapeutic that we are initially developing for the treatment of enteric hyperoxaluria in adults. Our second product candidate, ALLN-346, is being developed for patients with hyperuricemia and moderate to severe CKD. Hyperuricemia, or elevated levels of uric acid in the blood, is commonly associated with gout as well as kidney stones and kidney disorders.



* To be evaluated in a single Phase 2 clinical trial with a basket design that will enroll subsets of patients suffering from complications of severe hyperoxaluria, including adolescents and adults with primary hyperoxaluria or severe forms of secondary hyperoxaluria, both of which can lead to systemic oxalosis.

ALLN-177

We have conducted a robust clinical development program of ALLN-177 in healthy volunteers and patients with secondary hyperoxaluria. This program consisted of one Phase 1 clinical trial of 33 healthy volunteers and three Phase 2 clinical trials, which enrolled a total of 113 subjects with secondary hyperoxaluria, including the largest randomized, controlled trial of a novel therapeutic candidate specifically targeted at oxalate, which we refer to as Study 713. Our Phase 2 clinical program was designed to identify the optimal patient population, registrational endpoint and trial design for our planned pivotal Phase 3 program. As a result, we have developed key insights into hyperoxaluria, clinical trials in patients with hyperoxaluria and the activity and tolerability of ALLN-177 in this patient population.

We observed that ALLN-177 reduced 24 hour urinary oxalate excretion compared to placebo in patients with secondary hyperoxaluria, the overall population in Study 713. In this overall population, the magnitude of change

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did not reach statistical significance for the primary endpoint—reduction in urinary oxalate excretion from baseline to Week 4 of the trial. However, the data from pre-specified secondary endpoints and post-hoc analyses in the pre-specified subgroup of patients with enteric hyperoxaluria, which included 27% of the overall population (18/67) and 34% of the active treatment population (11/32) in Study 713, showed substantially greater reductions in urinary oxalate excretion in patients treated with ALLN-177 compared to placebo. Further, time-weighted average 24 hour urinary oxalate excretion over the four weeks of the trial, a pre-specified secondary endpoint in Study 713, achieved greater reductions in urinary oxalate excretion compared to placebo in both the overall population and the subgroup of patients with enteric hyperoxaluria. We believe this measurement to be an appropriate and clinically meaningful endpoint because it reflects the physiological effect of metabolic control of urinary oxalate excretion over time and dampens the effect of potential variability associated with 24 hour urinary oxalate excretion at any individual time point. In addition, our open-label Phase 2 clinical trial in secondary hyperoxaluria showed that ALLN-177 treatment resulted in greater reductions in urinary oxalate excretion in the enteric hyperoxaluria patient subgroup, which represented 31% of the overall patient population (5/16). Consequently, we believe our Phase 2 clinical program provided valuable insights with respect to both the study population—patients with enteric hyperoxaluria, and registrational endpoint—time-weighted average 24 hour urinary oxalate reduction, that we intend to carry forward in our planned pivotal Phase 3 program. In the aggregate, our clinical development program to date has demonstrated that:

- ALLN-177 can substantially reduce urinary oxalate excretion in patients with enteric hyperoxaluria;
- ALLN-177 has been well-tolerated, with no drug-related serious or severe adverse events; and
- the effect of ALLN-177 was specific to oxalate, with minimal to no changes in non-oxalate urine parameters.

We are in discussions with the FDA to finalize the design of our planned pivotal Phase 3 program for ALLN-177 in adult patients with enteric hyperoxaluria. We expect that this pivotal program will consist of two clinical trials evaluating efficacy and safety, one conducted primarily in the United States, and the other in the United States, Canada, Europe and potentially other geographies. We believe that these clinical trials will be sufficient to support our planned biologic license application, or BLA, assuming favorable results. We currently expect to initiate the first of these two Phase 3 clinical trials for ALLN-177 in the first quarter of 2018.

The FDA has granted separate orphan drug designations to ALLN-177 for the treatment of primary hyperoxaluria and for the treatment of pediatric hyperoxaluria. In addition, the European Commission has granted orphan designation for ALLN-177 for the treatment of primary hyperoxaluria. In light of these designations, we are planning to initiate a Phase 2 clinical trial in the first quarter of 2018 in adolescents and adults with primary hyperoxaluria or severe forms of secondary hyperoxaluria, both of which can lead to systemic oxalosis, a potentially fatal disorder, with interim data expected in the second half of 2018 and topline data anticipated in 2019.

Our Strategy

Our goal is to become the leader in developing and commercializing first-in-class, oral, non-absorbed enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders. To achieve this goal, we are executing on the following strategy:

- ***Obtain regulatory approval in the United States for our lead product candidate, ALLN-177, for enteric hyperoxaluria in adults***—We have conducted a robust Phase 2 clinical development program of ALLN-177 in patients with secondary hyperoxaluria, which demonstrated significant reductions of urinary oxalate excretion in patients with enteric hyperoxaluria. Based on these data and the high unmet need, we are initially developing ALLN-177 for enteric hyperoxaluria. Moreover, we believe the mechanism of action of ALLN-177, which degrades oxalate in the GI tract, is particularly well-targeted to treat enteric hyperoxaluria where excess oxalate absorption is driven by an underlying GI disorder. We

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are currently in discussions with the FDA to finalize the design of our planned pivotal Phase 3 program and we currently expect to initiate the first of two Phase 3 clinical trials for ALLN-177 in the first quarter of 2018, with topline data anticipated in the second half of 2019.

- ***Commercialize ALLN-177***—We have worldwide commercialization and development rights to ALLN-177. We intend to independently pursue regulatory approval of ALLN-177 in patients with enteric hyperoxaluria in the United States and, if approved, to commercialize the product by building a focused commercial organization in the United States specifically to target nephrologists and urologists who treat patients with hyperoxaluria, particularly at kidney stone clinics.
- ***Advance development of ALLN-177 for other severe forms of hyperoxaluria***—The FDA has granted separate orphan drug designations for ALLN-177 for the treatment of primary hyperoxaluria and for the treatment of pediatric hyperoxaluria (primary and secondary). In light of these designations, we are planning to initiate a Phase 2 clinical trial in the first quarter of 2018 in adolescents and adults with primary hyperoxaluria or severe forms of secondary hyperoxaluria, both of which can lead to systemic oxalosis, with interim data expected in the second half of 2018 and topline data anticipated in 2019. In addition, we plan to seek breakthrough designation where appropriate.
- ***Seek regulatory approval in Europe for our lead product candidate, ALLN-177***—We plan to pursue regulatory approval for patients with severe hyperoxaluria in Europe in conjunction with our pursuit of approval in the United States. We plan to obtain National Scientific Advice from select countries in Europe by the end of 2017 and to discuss the results of our Phase 2 clinical program in secondary hyperoxaluria and our proposed pivotal Phase 3 program in enteric hyperoxaluria. In addition, the European Commission has granted orphan designation for ALLN-177 for the treatment of primary hyperoxaluria.
- ***Advance development of ALLN-346***—Utilizing our expertise in enzyme therapeutics and proprietary technological approach, we have designed ALLN-346 to degrade urate in the GI tract. We intend to pursue the development of ALLN-346 for patients with hyperuricemia and CKD. These patients are challenging to manage due to limitations of existing therapies, such as poor tolerability, reduced efficacy, dose restriction or contraindications. We expect to initiate a preclinical proof of concept study for ALLN-346 in hyperuricemia animal models in the fourth quarter of 2017. Subject to the successful outcome of this study and customary toxicology preclinical studies, we expect to file an investigational new drug application (IND) for ALLN-346 in the first half of 2019.
- ***Explore collaboration opportunities for our product candidates in markets outside of the United States.*** We intend to explore collaborations to commercialize our product candidates, including ALLN-177, outside of the United States. However, depending on our evaluation of these market opportunities and the strategic merits of these collaboration opportunities, we may decide to retain commercial rights in key markets.

Competitive Strengths

We believe the following competitive strengths will help us achieve our strategy:

- Therapeutic focus on rare and severe metabolic disorders that affect the kidney and have high unmet medical needs due to the absence of approved or effective therapies;
- Lead product candidate, ALLN-177, with clear mechanism of action and consistent evidence of activity and tolerability across preclinical studies and multiple Phase 1 and 2 trials to support our planned pivotal Phase 3 program;
- Proprietary technological approach that allows us to design, formulate and deliver non-absorbed and stable enzymes orally and in sufficient doses for activity in the GI tract. This approach enables us to develop enzyme therapies that utilize the GI tract to degrade metabolites, such as oxalate and urate, reducing plasma and urine levels, and in turn, reducing their disease burden on the kidney over time;

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- Management team with substantial experience in developing and commercializing pharmaceutical products for metabolic and kidney disorders;
- Strong relationships with key opinion leaders and patient advocacy groups that provide access to the industry's leading experts on hyperoxaluria and other metabolic and kidney disorders; and
- Support from leading healthcare-focused investors and board members with experience in building and operating life science companies.

Our Team

We have assembled a seasoned management team with extensive experience in drug discovery, development, manufacturing and commercialization. We are supported by a top-tier investor syndicate including Frazier Healthcare Partners, Third Rock Ventures, Bessemer Venture Partners, HBM Healthcare Investments, Pharmstandard International S.A., Partner Fund Management, Fidelity Management & Research Company and other investors and have raised approximately $96.0 million in equity financing to date.

Risks Affecting Us

Our business is subject to a number of risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this prospectus summary. Some of these risks are:

- We are heavily dependent on the regulatory approval of ALLN-177 in the United States and Europe, and subsequent commercial success of ALLN-177, both of which may never occur.
- Results of earlier studies may not be predictive of future clinical trial results, and planned studies may not establish an adequate safety or efficacy profile for ALLN-177 and other product candidates that we may pursue to justify proceeding to an application for regulatory approval or be worthy of regulatory approval if such an application is made.
- We have not yet finalized the design of our pivotal Phase 3 clinical program for ALLN-177, including the primary and secondary endpoints and the statistical analyses for these planned Phase 3 clinical trials. The FDA and comparable foreign regulators may not agree with our proposed Phase 3 clinical program, in which case we may be required to modify our planned clinical trials, or run additional clinical trials, before we can submit a BLA or comparable foreign applications for this product candidate.
- We may attempt to secure approval from the FDA or comparable non-U.S. regulatory authorities through the use of accelerated registration pathways. If unable to obtain approval under an accelerated pathway, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining and/or delay the timing of obtaining, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.
- Because we are developing product candidates for the treatment of diseases in which there is little clinical trial experience and, in some cases, using new endpoints or methodologies, there is increased risk that the FDA or other regulatory authorities may not consider the endpoints of our clinical program to provide clinically meaningful results and that these results may be hard to analyze.
- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we

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believe they are, our revenue may be adversely affected, and our business may suffer. Our ability to successfully identify patients and acquire a significant market share will be necessary for us to achieve profitability and growth.

- We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do, and reducing or eliminating our commercial opportunity.
- We have relied, and will rely in the future, on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not appropriately carry out their contractual duties, fail to conduct high-quality studies or meet expected deadlines, regulatory approval and commercialization of ALLN-177 or any future candidates we may develop could be delayed or not obtained at all.
- The third parties upon whom we rely for the supply of the drug product and drug substance used in our lead product candidate are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.
- Our proprietary technological approach is a new approach to the design and development of stable, non-absorbable oral enzyme therapies and may not result in any additional product candidates or ultimately any products of commercial value.
- We have incurred significant losses since inception, expect to incur significant and increasing losses for at least the next several years, have not generated any revenue, may never generate any revenue, and may never achieve or maintain profitability.
- Even if we consummate this offering, we will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.
- If we are unable to obtain and maintain sufficient patent protection for our product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to commercialize our product candidates successfully may be adversely affected.

Corporate Information

We were incorporated under the laws of the State of Delaware and commenced business operations in 2011. Our principal executive offices are located at One Newton Executive Park, Suite 202, Newton, MA 02462 and our telephone number is (617) 467-4577. Our website address is www.allenapharma.com. The information contained on our website, or that can be accessed through our website, is not a part of this prospectus and is not incorporated by reference into this prospectus. You should not rely on any such information in deciding whether to purchase our common stock.

We own various U.S. federal trademark registrations and applications, and unregistered trademarks and service marks, including “Allena Pharmaceuticals” and our corporate logo. All trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies’ trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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Implications of Being an Emerging Growth Company

As a company with less than $1.07 billion in revenue during our most recently completed fiscal year, we qualify as an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable, in general, to public companies that are not emerging growth companies. These provisions include:

- reduced disclosure about our executive compensation arrangements;
- exemption from the non-binding stockholder advisory votes on executive compensation or golden parachute arrangements;
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting; and
- reduced disclosure of financial information in this prospectus, such as being permitted to include only two years of audited financial information and two years of selected financial information in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.07 billion in annual revenues as of the end of a fiscal year, have more than $700 million in market value of our capital stock held by non-affiliates as of any December 31 before that time or if we issue more than $1.0 billion of non-convertible debt over a three-year-period. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of some reduced reporting burdens in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

The JOBS Act permits an emerging growth company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

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THE OFFERING

Common stock offered by us	5,333,333 shares
Common stock to be outstanding immediately after this offering	20,621,848 shares
Underwriters' option to purchase additional shares	We have granted a 30-day option to the underwriters to purchase up to an aggregate of 800,000 additional shares of common stock.
Use of proceeds	We estimate that the net proceeds from the issuance of our common stock in this offering will be approximately $66.4 million, or approximately $76.9 million if the underwriters exercise their option to purchase additional shares in full, in each case after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and investments, as follows: (1) approximately $45.0 million for our planned pivotal Phase 3 clinical program of ALLN-177 for the treatment of patients with enteric hyperoxaluria; (2) approximately $3.0 million for our planned Phase 2 clinical trial of ALLN-177 in adolescents and adults with primary hyperoxaluria or severe forms of secondary hyperoxaluria; (3) approximately $3.0 million for our planned development of ALLN-346 for the treatment of patients with hyperuricemia and CKD; (4) approximately $8.0 million to fund our process validation and manufacturing batches for ALLN-177; and (5) the remainder for working capital and other general corporate purposes. See "Use of Proceeds" for additional information.
Risk factors	See "Risk Factors" and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Nasdaq Global Select Market symbol	"ALNA"

Certain of our existing stockholders who previously indicated an interest in purchasing shares of our common stock in this offering, including certain affiliates of our directors, have agreed to purchase an aggregate of approximately $20 million of shares of our common stock in this offering at the initial public offering price.

The number of shares of our common stock to be outstanding after this offering is based on 15,288,515 shares of our common stock outstanding as of June 30, 2017, after giving effect to the conversion of all outstanding shares of our preferred stock as of June 30, 2017 into an aggregate of 13,945,509 shares of common stock upon the completion of this offering and excludes:

- 1,394,299 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2017 at a weighted-average exercise price of $1.41 per share;
- 43,265 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2017 at a weighted-average exercise price of $5.55 per share;

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- 734,590 shares of common stock reserved for future issuance under our 2011 Stock Incentive Plan, or the 2011 Plan, as of June 30, 2017 which, upon the effectiveness of the registration statement of which this prospectus forms a part, became reserved for future issuance under our 2017 Stock Option and Incentive Plan, or the 2017 Plan, as reflected below;
- 2,038,021 shares of common stock reserved for future issuance under our 2017 Plan; and
- 206,284 shares of common stock reserved for the future issuance under our 2017 Employee Stock Purchase Plan.

Unless otherwise indicated, all information in this prospectus reflects or assumes the following:

- a 1-for-4.174 reverse stock split of our common stock effected on October 23, 2017;
- the conversion of all 58,208,614 of our outstanding shares of our preferred stock into 13,945,509 shares of common stock, which will occur immediately prior to the closing of this offering;
- no issuance or exercise of stock options or warrants on or after June 30, 2017 (which excludes the issuance of options to purchase an aggregate of 150,933 shares of common stock at a weighted-average exercise price of $5.67 per share after June 30, 2017); and
- no exercise by the underwriters of their option to purchase up to an additional 800,000 shares of common stock in this offering.

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SUMMARY CONSOLIDATED FINANCIAL DATA

The following summary consolidated financial data for the years ended December 31, 2015 and 2016 is derived from our audited consolidated financial statements included elsewhere in this prospectus. The summary consolidated financial data as of June 30, 2017 and for the six months ended June 30, 2016 and 2017 have been derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus. In the opinion of management, the unaudited condensed consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements and contain all adjustments, consisting of only normal recurring adjustments, that management considers necessary for the fair presentation of the financial information set forth in those statements. You should read this data together with our consolidated financial statements and related notes included elsewhere in this prospectus and the information under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results for any prior period are not necessarily indicative of results to be expected in any future period and our operating results for the six-month period ended June 30, 2017 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2017 or any other interim periods or any future year or period.

	Years Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
	(in thousands, except share and per share data)			
Consolidated Statement of Operations Data:				
Operating expenses:				
Research and development	$ 11,540	$ 20,103	$ 10,025	$ 7,809
General and administrative	2,365	4,083	2,057	2,208
Total operating expenses	13,905	24,186	12,082	10,017
Other income (expense):				
Interest income (expense), net	(335)	(200)	(71)	(255)
Other income (expense), net	(7)	(121)	1	(31)
Other income (expense), net	(342)	(321)	(70)	(286)
Net loss	$ (14,247)	$ (24,507)	$ (12,152)	$ (10,303)
Net loss per share attributable to common stockholders—basic and diluted(1)	$ (11.35)	$ (18.35)	$ (9.11)	$ (7.70)
Weighted-average common shares outstanding—basic and diluted(1)	1,258,123	1,339,254	1,337,100	1,342,628
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)(1)		$ (1.59)		$ (0.67)
Pro forma weighted-average common shares outstanding—basic and diluted (unaudited)(1)		15,284,763		15,288,137

(1) See Note 2 to our consolidated financial statements included elsewhere in this prospectus for a description of the method used to calculate basic and diluted net loss per share and unaudited pro forma basic and diluted net loss per share as well as the weighted-average number of common shares used in the calculation of the per share amounts.

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	June 30, 2017		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash, cash equivalents and investments	$ 37,962	$ 37,962	$ 104,402
Working capital(3)	34,142	34,142	100,582
Total assets	38,579	38,579	105,019
Loan payable, net of current portion and discount	7,553	7,553	7,553
Convertible preferred stock	95,761	—	—
Total stockholders' deficit	(69,414)	26,646	93,086

(1) The pro forma column reflects the automatic conversion of all 58,208,614 outstanding shares of our preferred stock into 13,945,509 shares of our common stock, which will occur immediately prior to the closing of this offering.

(2) The pro forma as adjusted column reflects the pro forma adjustments described in (1) above, and further reflects the sale of 5,333,333 shares of our common stock offered in this offering at the initial public offering price of $14.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities. See our consolidated financial statements for further details regarding our current assets and current liabilities.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in our common stock. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. Certain statements below are forward-looking statements. See "Special Note Regarding Forward-Looking Statements" in this prospectus.

Risks Related to Drug Development, Regulatory Approval and Commercialization

We are heavily dependent on the regulatory approval of ALLN-177 in the United States and Europe, and subsequent commercial success of ALLN-177, both of which may never occur.

We are a late-stage clinical biopharmaceutical company with no products approved by regulatory authorities or available for commercial sale. We have generated no revenue to date and do not expect to do so for the foreseeable future. As a result, our future success is currently dependent upon the regulatory approval and commercial success of ALLN-177 in one or more of the indications for which we seek approval. Our ability to generate revenues in the near term will depend on our ability to obtain regulatory approval and successfully commercialize ALLN-177 on our own in the United States, the first country in which we intend to make ALLN-177 available for sale, if approved. We may experience delays in obtaining regulatory approval in the United States for ALLN-177, if it is approved at all, and our stock price may be negatively impacted. Even if we receive regulatory approval, the timing of the commercial launch of ALLN-177 in the United States is dependent upon a number of factors, including, but not limited to, hiring sales and marketing personnel, pricing and reimbursement timelines, the production of sufficient quantities of commercial drug product and implementation of marketing and distribution infrastructure.

In addition, we have incurred and expect to continue to incur significant expenses as we continue to pursue the approval of ALLN-177 in the United States, Europe and elsewhere. We plan to devote a substantial portion of our effort and financial resources in order to continue to grow our operational capabilities. This represents a significant investment in the clinical and regulatory success of ALLN-177, which is uncertain. The success of ALLN-177, if approved, and revenue from commercial sales, will depend on several factors, including:

- execution of an effective sales and marketing strategy for the commercialization of ALLN-177;
- acceptance by patients, the medical community and third-party payors;
- our success in educating physicians and patients about the benefits, administration and use of ALLN-177;
- the incidence and prevalence of enteric hyperoxaluria in those markets in which ALLN-177 is approved;
- the prevalence and severity of side effects, if any, experienced by patients treated with ALLN-177;
- the availability, perceived advantages, cost, safety and efficacy of alternative treatments, including potential alternate treatments that may currently be available or in development or may later be available or in development or regulatory approval of a generic or biosimilar version of oxalate decarboxylase, the active enzyme in ALLN-177;
- successful implementation of our manufacturing processes that are included in our new biologics license application, or BLA, and production of sufficient quantities of commercial drug product;
- maintaining compliance with regulatory requirements, including current good manufacturing practices, or cGMPs, good laboratory practices, or GLP, and good clinical practices, or GCPs; and

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- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity and otherwise protecting our rights in our intellectual property portfolio.

We may also fail in our efforts to develop and commercialize future product candidates, including ALLN-346 for patients with hyperuricemia and chronic kidney disease, or CKD. If this were to occur, we would continue to be heavily dependent on the regulatory approval and successful commercialization of ALLN-177, our development costs may increase and our ability to generate revenue or profits, or to raise additional capital, could be impaired.

Results of earlier studies may not be predictive of future clinical trial results, and planned studies may not establish an adequate safety or efficacy profile for ALLN-177 and other product candidates that we may pursue to justify proceeding to an application for regulatory approval or be worthy of regulatory approval if such an application is made.

The results of preclinical studies and clinical trials of ALLN-177 conducted to date and future studies and trials of other product candidates that we may pursue may not be predictive of the results of later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. Data, our interpretation of data and results from our Phase 2 clinical trials of ALLN-177 in adults with enteric hyperoxaluria do not ensure that we will achieve similar results in a pivotal Phase 3 clinical trial in enteric hyperoxaluria or in clinical trials of ALLN-177 in other patient populations. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and early-stage clinical trials have nonetheless failed to replicate results in later-stage clinical trials and subsequently failed to obtain marketing approval. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and initial clinical trials.

In particular, as is common with Phase 2 clinical trials, particularly with the first clinical trials to be conducted in a patient population with disease, we explored numerous endpoints and analyzed the data from our Phase 2 clinical trials of ALLN-177 in a number of ways. Prior to obtaining approval for ALLN-177, we expect that the results of our registration trials will have to demonstrate statistically significant improvement in the pre-specified primary endpoint in the applicable registration trial. To date, two of our Phase 2 clinical trials of ALLN-177 (Study 713 and Study 649) have not demonstrated statistically significant results in the pre-specified primary endpoints. Our later-stage clinical trials will differ in significant ways from our Phase 2 clinical trials of ALLN-177, which may cause the outcome of these later-stage trials to differ from our earlier stage clinical trials. These differences may include changes to inclusion and exclusion criteria, efficacy endpoints and statistical design. We are still finalizing the design of our planned pivotal Phase 3 clinical program for ALLN-177, including the primary and secondary endpoints and statistical analysis plan for these trials.

Product candidates in Phase 3 clinical trials, such as ALLN-177 in our planned pivotal Phase 3 clinical program, may fail to demonstrate sufficient efficacy despite having progressed through initial clinical trials, even if certain analyses of primary or secondary endpoints in those early trials showed trends toward efficacy. Some of the data we present on the use of ALLN-177 for the treatment of enteric hyperoxaluria is drawn from post-hoc analyses. While we believe these data are useful in informing the design of future clinical trials for ALLN-177, these analyses involve the inherent bias of post-hoc rendering of data and choice of analytical methods. Further, while Study 713 was the largest randomized, controlled trial ever conducted in hyperoxaluria, only 18 subjects with enteric hyperoxaluria, the proposed indication for our planned pivotal Phase 3 program, enrolled in the trial. Thus, we have limited data on the activity of ALLN-177 in the target population for our planned Phase 3 clinical program.

We believe 24 hour urinary oxalate excretion is an appropriate metric of the therapeutic effect of ALLN-177 because 24 hour urinary oxalate excretion is a biochemical measurement of the daily amount of oxalate handling by the kidney and therefore its reduction would indicate lessening of potential kidney damage by oxalate. However, based on published scientific literature and data generated in our own clinical trials, daily urinary oxalate excretion is a biomarker that demonstrates significant variability between patients and day-to-day for the

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same patient. This variability in 24 hour urinary oxalate excretion, especially in enteric hyperoxaluria patients, can be attributed to changes in diet, metabolic activity, hydration status or other factors. It can also be attributed to the manner in which these measurements are taken. In our completed Phase 2 clinical trials, we relied heavily on the efforts and contributions of investigative clinical sites and study patients to comply with accurate timing of 24 hour urine collection, with the complete collection of all of the patient's urine during a given 24 hour period and with the proper handling of collected urine specimens, including storage, documentation, sample handling and shipping to the testing laboratory. Following our completed Phase 2 clinical trials, we conducted a post-hoc review of these collection procedures. Although we are not aware of any case where the data reported in our prior clinical trials was inaccurate, due to the variability inherent in these data collection techniques, we cannot assure you that in all cases the data reported in our clinical trials accurately reflect the actual biochemical responses experienced by patients in these trials. We believe a time-weighted average of daily urinary oxalate excretion mitigates the risks of inherent variability, dietary change and sample handling associated with the testing of each individual 24 hour urine specimen, but no assurance can be given that any such variability will be fully addressed by this approach.

A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. Even if early stage clinical trials are successful, we may need to conduct additional clinical trials for product candidates in additional patient populations or under different treatment conditions before we are able to seek approvals from the U.S. Food and Drug Administration, or FDA, and comparable foreign regulators to market and sell these product candidates. Our failure to demonstrate the required characteristics to support marketing approval for ALLN-177 or any other product candidate we may choose to develop in any ongoing or future clinical trials would substantially harm our business, prospects, financial condition and results of operations.

We have not yet finalized the design of our pivotal Phase 3 clinical program for ALLN-177, including the primary and secondary endpoints and the statistical analyses for these planned Phase 3 clinical trials. The FDA and comparable foreign regulators may not agree with our proposed Phase 3 clinical program, in which case we may be required to modify our planned clinical trials, or run additional clinical trials, before we can submit a BLA and comparable foreign applications for this product candidate.

We are in discussions with the FDA to finalize the design of our pivotal Phase 3 program for ALLN-177 in adult patients with enteric hyperoxaluria, including the primary and secondary endpoints and the statistical analyses for these planned Phase 3 clinical trials. There can be no assurance that we will reach agreement with the FDA on our Phase 3 clinical program as currently proposed. For example, we have proposed as a primary endpoint the proportion of patients with ≥ 20% reduction in time-weighted average, or TWA, 24 hour urinary oxalate, or UOx, excretion from baseline. The FDA has advised us that it may be willing to accept a substantial change in 24 hour UOx excretion as a surrogate endpoint in patients with secondary hyperoxaluria, especially patients with enteric hyperoxaluria, a prior history of kidney stones and very high baseline levels of UOx excretion, most likely as the basis for an accelerated approval. However, the FDA has also advised us that we have not yet provided sufficient data regarding the magnitude of effect on UOx excretion necessary to support its use as a primary endpoint for these clinical trials. We are currently assembling and analyzing available data from third-party clinical databases in order to develop a quantitative predictive model that further substantiates the relationship between the change in 24 hour UOx excretion and the change in specific outcomes of interest (*e.g.*, stone formation) in the target hyperoxaluric patient populations. If the FDA agrees to accept a change in TWA 24 hour UOx excretion as the primary endpoint for our pivotal Phase 3 program under the accelerated approval pathway, we will be required to provide study data on longer term clinical follow up from trial patients, or conduct a separate clinical outcomes trial, to confirm the clinical benefit predicted by the biochemical therapeutic response demonstrated in our Phase 3 clinical trials. The FDA may require demonstration that we have initiated or made substantial progress in our clinical follow up of trial subjects, or any such clinical outcomes trial, prior to the submission of our BLA for accelerated approval of ALLN-177. If we are unable to reach consensus with the FDA on the magnitude of UOx reduction significant enough to predict clinical benefit, we may be required to

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demonstrate effectiveness by showing an effect on stone formation directly, or conduct one or more additional clinical trials to demonstrate this effect, prior to the submission of a BLA for ALLN-177. Moreover, the FDA may require us to make other changes to our proposed design of our Phase 3 clinical program for ALLN-177, including expanding the number of patients and/or treatment period evaluated or running one or more additional clinical trials prior to the submission of a BLA. Any of these decisions could have a material adverse effect on our expected clinical and regulatory timelines, business, prospects, financial condition and results of operations.

Similarly, our planned Phase 3 program may not be sufficient to support the submission of applications for marketing approval in foreign jurisdictions, including the European Union. Although our preliminary discussions with regulatory authorities in select countries within the European Union lead us to believe our planned Phase 3 program, if successful, may be sufficient to support the submission of an MAA in Europe, these discussions are not binding on such authorities or the EMA. Accordingly, no assurance can be given that our planned Phase 3 program will be sufficient to support the submission of an MAA in Europe, and we may be required to modify the design of these planned trials, or run additional clinical trials, before seeking marketing approval. Any of these decisions could have a material adverse effect on our expected clinical and regulatory timelines, business, prospects, financial condition and results of operations.

We may attempt to secure approval from the FDA or comparable non-U.S. regulatory authorities through the use of accelerated registration pathways. If unable to obtain approval under an accelerated pathway, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining and/or delay the timing of obtaining, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We may seek an accelerated approval development pathway for our product candidates, including ALLN-177. Under the accelerated approval provisions of the Federal Food, Drug, and Cosmetic Act and the FDA's implementing regulations, the FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic advantage over available therapies and demonstrates an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval development pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical profile or risks and benefits for accelerated approval. The FDA may require that any such confirmatory study be initiated or substantially underway prior to the submission of an application for accelerated approval. If such post-approval studies fail to confirm the drug's clinical profile or risks and benefits, the FDA may withdraw its approval of the drug.

If we choose to pursue accelerated approval, we intend to seek feedback from the FDA or will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that the FDA will agree that our proposed primary endpoint for our planned pivotal Phase 3 clinical program is an appropriate surrogate endpoint. There also can be no assurance that, after our evaluation of the feedback from the FDA or other factors, we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback that we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we submit an application for accelerated approval, there can be no assurance that such application will be accepted or that approval will be granted on a

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timely basis, or at all. For example, if another company receives full approval from the FDA to market a product for treatment of hyperoxaluria, our ability to seek and obtain accelerated approval for ALLN-177 in the same or similar indication may be materially adversely affected. The FDA or foreign regulatory authorities also could require us to conduct further studies or trials prior to considering our application or granting approval of any type. We might not be able to fulfill the FDA's requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA. A failure to obtain accelerated approval or any other form of expedited development, review or approval for a product candidate would result in a longer time period to commercialize such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Even if we receive accelerated approval from the FDA, we will be subject to rigorous post-marketing requirements, including the completion of confirmatory post-market clinical trial(s) to verify the clinical benefit of the product, and submission to the FDA of all promotional materials prior to their dissemination. The FDA could seek to withdraw accelerated approval for multiple reasons, including if we fail to conduct any required post-market study with due diligence, a post-market study does not confirm the predicted clinical benefit, other evidence shows that the product is not safe or effective under the conditions of use, or we disseminate promotional materials that are found by the FDA to be false and misleading

A failure to obtain accelerated approval or any other form of expedited development, review or approval for a product candidate that we may choose to develop would result in a longer time period prior to commercializing such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Because we are developing product candidates for the treatment of diseases in which there is little clinical trial experience and, in some cases, using new endpoints or methodologies, there is increased risk that the FDA or other regulatory authorities may not consider the endpoints of our clinical program to provide clinically meaningful results and that these results may be hard to analyze.

There are no pharmacologic therapies approved to treat the underlying causes of hyperoxaluria. In addition, it should be noted that no therapeutic agents have previously been approved by the FDA on the basis of a biochemical measurement of 24 hour urinary oxalate excretion, endpoints used in our Phase 2 clinical program and expected for our planned pivotal Phase 3 clinical program. As a result, the design and conduct of clinical trials for the treatment of hyperoxaluria, and the underlying conditions and disorders that drive the metabolic disease, are subject to increased risk.

We have engaged in discussions with the FDA during our end of Phase 2 meeting, and subsequently, regarding the design of our planned pivotal Phase 3 clinical program for ALLN-177 in adult patients with enteric hyperoxaluria. While we have received initial feedback, we do not yet have definitive feedback from the FDA on the proposed primary endpoint of our planned pivotal Phase 3 clinical program, the measure of what is clinically meaningful in respect of this endpoint, secondary endpoints and the requisite data necessary to justify an approval. Furthermore, the FDA has discretion to reserve judgment on whether our endpoint and the results seen in our planned pivotal Phase 3 clinical program sufficiently demonstrate clinical meaningfulness until the FDA reviews our BLA several years from now.

Moreover, even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a degree of statistical significance, in either or both of the Phase 3 clinical trials that we believe will be necessary for approval. Further, even if we do achieve the pre-specified criteria, we may produce results that are unpredictable or inconsistent with the results of the secondary efficacy endpoints in the trials. The FDA also could give overriding weight to other efficacy endpoints, even if we achieve statistically significant results on the primary endpoint, if we do not achieve statistically significant or clinically meaningful results on any of our secondary efficacy endpoints. The FDA also weighs the benefits of a product against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of regulatory approval. Other regulatory authorities in the EU and other countries may take similar positions.

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The design and conduct of clinical trials is complex, particularly where there is not an established regulatory approval pathway for a given patient population, such as enteric hyperoxaluria, or a new mechanism of action is being tested, as this may result in unpredictable results. For example, in our Phase 2 clinical trial referred to as Study 649, a "crossover" trial design was used, which is a longitudinal study in which subjects receive a sequence of different exposures during the course of the trial. Each treatment sequence consisted of two seven-day treatment periods separated by a seven-day washout period. While no clear factor was identified to account for the lack of differentiation between ALLN-177 and placebo in Study 649, we believe the lack of effect may have been due to, among other things, the complexities inherent in the crossover study design.

In addition, we are planning to conduct a Phase 2 clinical trial of ALLN-177 utilizing an open-label, basket trial design that will enroll subsets of patients suffering from complications of severe hyperoxaluria, including adolescents and adults with primary hyperoxaluria or severe forms of secondary hyperoxaluria, both of which can lead to systemic oxalosis. We have not yet evaluated ALLN-177 in patients with primary hyperoxaluria and as such we have not yet demonstrated proof-of-concept in this patient population. Basket trial designs permit the exploration of a study drug in patient populations with common biochemical markers, such as patients afflicted with different forms of cancer, but the same genetic mutation. Although all patients enrolled in our planned Phase 2 trials will have elevated urinary oxalate levels, the underlying cause of their hyperoxaluria may be different. We cannot predict whether the design of our planned pivotal Phase 3 clinical program, the Phase 2 basket trial or any other future trials that we may conduct may successfully demonstrate ALLN-177 or any future product candidate's safety and efficacy.

If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA and other comparable foreign regulators, we, or any future collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates.

We, and any future collaborators, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Comparable foreign regulators, such as the European Medicines Agency, or EMA, impose similar restrictions. We, and any future collaborators, may never receive such approvals. We, and any future collaborators, must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we, or they, will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We have not previously submitted a BLA to the FDA or similar drug approval applications to comparable foreign regulators for any of our product candidates. Any inability to complete preclinical and clinical development successfully could result in additional costs to us, or any future collaborators, and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. Moreover, if (1) we, or any future collaborators, are required to conduct additional clinical trials or other testing of our product candidates beyond the trials and testing that we, or they contemplate, (2) we, or any future collaborators, are unable to successfully complete clinical trials of our product candidates or other testing, (3) the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or (4) there are unacceptable safety concerns associated with our product candidates, we, or any future collaborators, may:

- incur additional unplanned costs;
- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;

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- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval.

Our failure to successfully complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business, prospects, financial condition and results of operations.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Our planned pivotal Phase 3 clinical program for ALLN-177 consists of two Phase 3 clinical trials of ALLN-177 in adult patients with enteric hyperoxaluria. We are in discussions with the FDA and expect to engage foreign regulators before the end of the year regarding the design of these trials. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other comparable foreign regulators could disagree that we have satisfied their requirements to commence our clinical trials or change their position on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. We may need to conduct additional clinical trials or other testing for, among other things, drug-drug interactions, the generation of formate (i.e. a metabolic byproduct resulting from the degradation of oxalate by ALLN-177) and increased dosages of our product candidates. Successful completion of our clinical trials is a prerequisite to submitting a BLA to the FDA and a Marketing Authorization Application, or MAA, in Europe for each product candidate and, consequently, the ultimate approval and commercial marketing of ALLN-177, ALLN-346 and any product candidates we may develop in the future. We do not know whether any of our clinical trials will begin or be completed on schedule, if at all.

We may experience delays in initiating or completing our planned clinical trials or additional preclinical studies or clinical trials in the future, and we may experience numerous unforeseen events during, or as a result of, any future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience delays in recruiting, or be unable to recruit, a sufficient number of suitable patients to participate in our clinical trials;
- the patients and sites who participate in our trials may not comply with protocols, such as compliance with the capsule and timing regimen and urine collection requirements, rendering the results insufficient or uninterpretable**;**
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third party contractors may fail to comply with regulatory or legal requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;

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- we may elect to, or regulators or IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- the occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- any changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other therapies that raise safety or efficacy concerns about our product candidates; and
- the FDA or other comparable foreign regulators may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other comparable foreign regulators. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, GCP or our clinical protocols, inspection of the clinical trial operations or trial sites by the FDA or other comparable foreign regulators resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

Our drug development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. Any delays in our preclinical or clinical development programs may significantly harm our business, prospects, financial condition and results of operations.

The regulatory approval processes of the FDA and comparable foreign regulators are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for ALLN-177 or our other product candidates, our business will be substantially harmed.

We are not permitted to market ALLN-177 or any of our other product candidates in the United States or the European Union, or EU, until we receive approval of a BLA from the FDA or an MAA from the EMA, respectively. Prior to submitting a BLA to the FDA or an MAA to the EMA for approval of any of our product candidates for a specific indication, we are required to complete preclinical and toxicology studies, as well as Phase 1, Phase 2 and Phase 3 clinical trials.

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Successfully initiating and completing our clinical program and obtaining approval of a BLA or an MAA is a complex, lengthy, expensive and uncertain process, and the FDA, the EMA or other comparable foreign regulators may delay, limit or deny approval of any of our candidates for many reasons, including, among others:

- we may not be able to demonstrate that our product candidates are safe and effective to the satisfaction of the FDA or the EMA;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or the EMA for marketing approval;
- the FDA or the EMA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or the EMA may require that we conduct additional clinical trials;
- the FDA or the EMA or other applicable foreign regulators may not approve the formulation, labeling or specifications of ALLN-177 or our other product candidates;
- the CROs that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA or the EMA may find the data from preclinical studies and clinical trials insufficient to demonstrate that the clinical and other benefits of ALLN-177 and our other product candidates outweigh their safety risks;
- the FDA or the EMA may disagree with our interpretation of data from our preclinical studies and clinical trials, including our characterization of observed toxicities;
- the FDA or the EMA may not accept data generated at our clinical trial sites;
- if our BLAs or MAAs, if and when submitted, are reviewed by the FDA or the EMA, as applicable, the regulatory agency may have difficulties scheduling the necessary review meetings in a timely manner, may recommend against approval of our application or may recommend that the FDA or the EMA, as applicable, require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy as a condition of approval or post-approval, and the EMA may grant only conditional approval or impose specific obligations as a condition for marketing authorization, or may require us to conduct post-authorization safety studies;
- the FDA, the EMA or other applicable foreign regulators may find deficiencies with or not approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the FDA or the EMA may change their approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market ALLN-177 or any of our other product candidates. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

In addition to the United States and Europe, we or potential collaborators intend to market our product candidates, if approved, in other international markets. Such marketing will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary from country-to-country and may require additional testing. Moreover, the time required to obtain approval may differ from that required to obtain FDA or EMA approval. In addition, in many countries, a product candidate must be approved for reimbursement before it can be approved for sale in that country, even if regulatory approval has been obtained. Approval by the FDA or the EMA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA or the EMA. The regulatory approval process in other international markets may include all of the risks associated with obtaining FDA or EMA approval.

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Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

The FDA's and other comparable foreign regulators' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of ALLN-177 and any future product candidates we may develop. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the EU or other countries or jurisdictions. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would harm our business, prospects, financial condition and results of operations.

If we are required to conduct additional clinical trials or other studies with respect to ALLN-177 or any future product candidates we may develop beyond those that we currently contemplate, or if we are unable to successfully complete our clinical trials or other studies, we may be delayed in obtaining regulatory approval of ALLN-177 and any future product candidates we may develop, we may obtain approval of indications that are not as broad as intended or we may not be able to obtain regulatory approval at all. Our product development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for ALLN-177 or any future product candidates we may develop. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business would be harmed.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulators. In particular, because we are focused on patients with enteric hyperoxaluria with respect to our Phase 3 development of ALLN-177, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

Patient enrollment may be affected by other factors including, but not limited to:

- the severity of the disease under investigation;
- the design of the clinical trial;
- the size and nature of the patient population;
- the eligibility criteria for the clinical trial in question;
- the availability of appropriate screening tests for study subjects;
- the perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies or treatment approaches;
- the efforts to facilitate timely enrollment in clinical trials;
- the ability to obtain and maintain patient consents and the risk that patients enrolled in clinical trials will not complete a clinical trial;
- the patient referral practices of physicians;

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- the ability of patients to comply with the protocol, including capsule and timing regimen and urine collection requirements;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; and
- the extent to which our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drugs.

If the FDA, the EMA or a comparable foreign regulator approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the drug. Later discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary drug recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug approvals;
- drug seizure or detention, or refusal to permit the import or export of the drug; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Accordingly, assuming we, or any collaborators we may have, receive marketing approval for one or more product candidates we develop, we, and such collaborators, and our and their contract manufacturers will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, and quality control. If we and such collaborators are not able to comply with post-approval regulatory requirements, we and such collaborators could have the marketing approvals for our products withdrawn by regulatory authorities and our, or such collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition, and prospects.

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We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do, and reducing or eliminating our commercial opportunity.

Our industry is highly competitive and subject to rapid and significant technological change as researchers learn more about diseases and develop new technologies and treatments. Our potential competitors include primarily large pharmaceutical, biotechnology companies and specialty pharmaceutical companies. Key competitive factors affecting the commercial success of ALLN-177, ALLN-346 and any other product candidates we may develop are likely to be efficacy, safety and tolerability profile, reliability, convenience of administration, price and reimbursement.

There is no approved pharmacologic therapy for the reduction of urinary oxalate excretion in patients with hyperoxaluria, either primary or secondary. Existing treatment options for hyperoxaluria generally are non-specific and include high fluid intake to increase urine output to more than two to three liters per day, a diet low in salt and oxalate, oral citrate and/or calcium and/or magnesium supplementation and orthophosphate and Vitamin B6, exclusively for the specific subset of responsive patients with the most severe form of primary hyperoxaluria (PH1).

We are aware of other companies pursuing oxalate reduction in both primary and secondary hyperoxaluria. Alnylam and Dicerna are developing injectable gene-silencing technologies using RNA, with product candidates focused on addressing primary hyperoxaluria. Both are in early-stage clinical development. Oxthera AB (Sweden) and Captozyme (U.S.) are developing orally delivered products to degrade oxalate in the stomach and GI tract. Oxthera is advancing oxabact, *Oxalobacter formigenes*, into Phase 3 clinical trials for the treatment of primary hyperoxaluria.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a small number of our competitors. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval of drugs and achieving widespread market acceptance. Our competitors' drugs, or drugs they may develop in the future, may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render ALLN-177 or any future product candidates we may develop obsolete or non-competitive before we can recover the expenses of developing and commercializing ALLN-177 or any future product candidates we may develop. Our competitors may also obtain FDA or other regulatory approval of their products more rapidly than we may obtain approval of ours. Our competitors could develop and the FDA could approve a generic or biosimilar version of oxalate decarboxylase, the active enzyme in ALLN-177. We anticipate that we will face intense and increasing competition as new drugs enter the market and more advanced technologies become available. If we are unable to compete effectively, our opportunity to generate revenue from the sale of ALLN-177 or any future product candidates we may develop, if approved, will be adversely affected.

The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer. Our ability to successfully identify patients and acquire a significant market share will be necessary for us to achieve profitability and growth.

We focus our research and product development on treatments for hyperoxaluria and hyperuricemia. The precise incidence and prevalence for these diseases are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. For example, we estimate there are approximately 200,000 to 250,000 patients in the United States with enteric hyperoxaluria and kidney stones. This estimate has been derived from a variety of sources, including the scientific literature and market research projects with third-party consultants, and may prove to be incorrect. Further, new studies and future

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developments in patient care or treatment paradigms may change the estimated incidence or prevalence of this disorder. The number of patients may turn out to be lower than expected. The potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for one or more of our product candidates, because certain of our potential target populations are small, including our target populations for which ALLN-177 has received orphan drug designation, we may never achieve profitability despite obtaining such significant market share.

Even if one of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for such product candidate may be smaller than we estimate.

We have never obtained marketing approval for a product candidate or commercialized a product. Even if one of our product candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any one of our product candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the potential advantages of the product compared to alternative treatments;
- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved;
- the potential absence of the results of a late-stage clinical trial with a clinically meaningful primary endpoint;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- the strength of our sales, marketing and distribution support;
- the approval of other new products for the same indications;
- changes in the standard of care for the targeted indications for the product;
- the timing of market introduction of our approved products as well as competitive products;
- availability and amount of reimbursement from government payors, managed care plans and other third-party payors;

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- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

The potential market opportunities for our product candidates are difficult to estimate precisely. Our estimates of the potential market opportunities are predicated on many assumptions, including industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities, which would adversely affect our results of operations and our business.

Our proprietary technological approach is a new approach to the design and development of stable, non-absorbable oral enzyme therapies and may not result in any additional product candidates or ultimately any products of commercial value.

We have developed our proprietary know-how in enzyme technology which allows us to design, formulate and deliver non-absorbed and stable enzymes orally and in sufficient doses for activity in the GI tract. While the general therapeutic approach of deploying a non-absorbed drug into the GI tract to reduce metabolic disease burden in patients with kidney disease has been proven successful in several therapeutic categories, we cannot assure you that our technological approach will ultimately work for ALLN-177, ALLN-346, or any other product candidates we may develop. In addition, while we believe our enzyme therapeutic candidates will not be absorbed, future clinical trials may find this not to be true. We also cannot guarantee that any other aspects of our proprietary technological approach will yield product candidates that could receive regulatory approval, enter clinical development and, ultimately, be commercially valuable.

We only have a limited number of employees to manage and operate our business.

As of June 30, 2017, we had 29 full-time, part-time, or short-term employees. Our focus on the development of ALLN-177 requires us to optimize cash utilization and to manage and operate our business in a highly efficient manner. We will need to hire and retain a significant number of new employees to execute our clinical development and manufacturing plans. We cannot provide assurance that we will be able to hire and/or retain adequate staffing levels to develop ALLN-177 or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

We currently have no sales and marketing organization and, as a company, have not commercialized any products. If we are unable to establish effective sales and marketing capabilities in the United States and access them in Europe and other international markets, we may not succeed in commercializing our product candidates.

At present, we have no sales or marketing employees and we rely on part-time consultants. We cannot guarantee that we will be successful in marketing ALLN-177 for enteric hyperoxaluria in the United States, if approved. We may not be able to establish a direct sales force in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize ALLN-177 in the United States without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of our planned relatively small sales force to obtain access to or inform adequate numbers of nephrologists, urologists or other practitioners at kidney stone clinics;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;

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- the inability of market-access personnel to obtain sufficient levels of pricing and reimbursement in each jurisdiction; and
- unforeseen costs, expenses and delays associated with creating a commercial organization.

If we are not successful in timely recruiting of sales and marketing personnel or in building a sales and marketing infrastructure or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty commercializing ALLN-177, which could harm our business, operating results and financial condition. Expansion of our business into the EU and other international markets will require significant management attention and additional financial resources. We currently intend to explore commercializing ALLN-177, if approved, in Europe and other international markets by entering into collaboration agreements with other biopharmaceutical companies, and we may not be successful in entering into these collaboration agreements. In the event that we do enter into such agreements, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Additional factors and risks that may inhibit our efforts to commercialize ALLN-177 in foreign markets include:

- our inability to directly control commercial activities because we are relying on third parties, should we enter into third-party collaborations;
- varying pricing in different foreign markets, which could adversely affect pricing in the United States or other countries;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer collection times for accounts receivable;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics;
- the imposition of governmental price controls, political and economic instability, trade restrictions and changes in tariffs;
- foreign currency exchange rate fluctuations;
- our customers' ability to obtain adequate reimbursement for ALLN-177 in foreign markets at all, either at all or at prices that exceed our costs; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Our future revenues may depend heavily on the success of the efforts of these third parties. We may not be able to establish a commercial operation in a cost-effective manner or realize a positive return on this investment, even with the assistance of one or more third-party collaborators, should we choose to enter into such an arrangement. In addition, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel.

If we or third-party collaborators are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure or if we do not successfully enter into additional collaboration arrangements with third parties, we may not be able to successfully commercialize ALLN-177 and any future product candidates we may develop in foreign markets, which could impair our business, operating results and financial condition.

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Even with the potential assistance of third-party collaborators, we may not be successful in establishing a commercial operation in foreign markets for numerous reasons, including, but not limited to, failing to attract, retain and motivate the necessary skilled personnel and failing to develop a successful marketing strategy. Failure to establish a commercial operation in foreign markets will have a negative outcome on our ability to commercialize ALLN-177 and generate revenue.

Additionally, if approved for marketing in one or more countries, we and/or our potential third-party collaborators may encounter unexpected or unforeseen delays in establishing our commercial operations that delay the commercial launch in these countries. These delays may increase the cost of and the resources required for successful commercialization of ALLN-177 internationally. We do not have any experience in a commercial launch in Europe or elsewhere.

We expect to expand our development, regulatory, and future sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, manufacturing, regulatory affairs, and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources and attention. Any inability to manage growth could delay the execution of our business plans or disrupt our operations, which could affect our ability to generate revenue.

The manufacture and packaging of pharmaceutical products such as ALLN-177 are subject to FDA requirements and those of similar foreign regulatory bodies. If we or our third-party manufacturers fail to satisfy these requirements, our product development and commercialization efforts may be harmed.

The manufacture and packaging of pharmaceutical products, such as ALLN-177, if approved, are regulated by the FDA and similar foreign regulatory bodies and must be conducted in accordance with the FDA's cGMP and comparable requirements of foreign regulatory bodies. There are a limited number of manufacturers that operate under these cGMP regulations who are both capable of manufacturing ALLN-177 and willing to do so. We may not be able to identify or secure contracts with manufacturers with suitable capability to manufacture ALLN-177 according to FDA requirements on favorable terms or at all. Failure by us or our third-party manufacturers to comply with applicable regulations or requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product, operating restrictions and criminal prosecutions, any of which could harm our business. The same requirements and risks are applicable to the suppliers of the key raw material used to manufacture ALLN-177, including the specific bacterial strains that are used to manufacture the oxalate decarboxylase enzyme, which is an active ingredient in ALLN-177.

Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval of the manufacturing process and procedures in accordance with the FDA's cGMPs. Any new facility is subject to a pre-approval inspection by the FDA and would again require us to demonstrate product comparability to the FDA. There are comparable foreign requirements. This review may be costly and time consuming and could delay, constrain or prevent the launch or supply of a product.

Furthermore, in order to obtain approval of our product candidates, including ALLN-177, by the FDA and foreign regulatory agencies, we will be required to consistently produce the drug substance and the finished

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product in commercial quantities and of specified quality on a repeated basis and document our ability to do so. This requirement is referred to as process validation. We have not yet met with the FDA or foreign regulatory agencies to understand the complete manufacturing requirements which must be met for ALLN-177 to receive regulatory approval. Each of our potential suppliers will likely use a different method to manufacture drug substance, which has the potential to increase the risk to us that our manufacturers will fail to meet applicable regulatory requirements. We also need to complete process validation on the finished product in the packaging we propose for commercial sales. This includes testing of stability, measurement of impurities and testing of other product specifications by validated test methods. If the FDA or foreign regulatory agencies do not consider the result of the process validation or required testing to be satisfactory, we may not obtain approval to launch the product or approval, launch or availability of commercial supply after launch may be delayed.

The FDA and similar foreign regulatory bodies may also implement new requirements, or change their interpretation and enforcement of existing requirements, for manufacture, packaging or testing of products at any time. If we are unable to comply, we may be subject to regulatory, civil actions or penalties which could harm our business.

Manufacture and supply of drug substance, drug product and finished drug product is a complex and technically challenging undertaking, particularly for oral biologics, and there is potential for failure at many points in the manufacturing, testing, quality assurance and distribution supply chain, as well as the potential for latent defects after a product has been manufactured and distributed.

Manufacture and supply of drug substance, drug product and finished drug product is technically challenging, particularly for oral biologics. Changes that may be made outside the purview of our direct control can have an impact on the success of our processes, on quality, and on successful delivery of finished drug product. Mistakes and mishandling could affect successful production and supply. Some of these risks include:

- failure to follow cGMP requirements or mishandling of our product while in production or in preparation for transit;
- delays in analytical results or failure of analytical techniques that we depend on for quality control and release of drug product;
- natural disasters, labor disputes, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations at our manufacturing facilities; and
- latent defects that may become apparent after drug product has been released and which may result in recall or required destruction of drug product.

If any of these risks materialize, it would have a material and adverse impact on our ability to develop, obtain regulatory approval for and market ALLN-177, if approved.

The longer term growth of our business depends on our ability to expand our portfolio of product candidates, which may require substantial financial resources and may ultimately be unsuccessful.

The longer term growth of our business depends upon our ability to develop and commercialize multiple product candidates. In addition to the development and commercialization of ALLN-177 for hyperoxaluria, we intend to pursue development of ALLN-346 for hyperuricemia and CKD as well as other product candidates. We may never be able to identify other developmental prospects that we can successfully develop into product candidates, let alone receive regulatory approval of or successfully commercialize such product candidates.

A significant portion of the research that we are conducting involves new technologies. Research programs to identify new disease targets and product candidates require substantial technical, financial and human resources whether or not we ultimately identify any product candidates. Our research programs may initially

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show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including, but not limited to:

- the research methodology used may not be successful in identifying potential product candidates; or
- potential product candidates may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective drugs.

There are a number of FDA requirements that we must satisfy before we can commence a clinical trial in the United States. If we are able to identify additional potential product candidates, satisfaction of these regulatory requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. Any time, effort and financial resources we expend on development of other product candidates may impair our ability to continue efforts to develop and commercialize ALLN-177 for the treatment of enteric hyperoxaluria and other indications, and we may never commence clinical trials of such development programs despite expending significant resources in pursuit of their development. If we do commence clinical trials of other product candidates, those product candidates may never demonstrate sufficient safety and efficacy to be approved by the FDA or other comparable foreign regulators. If any of these events occur, we may be forced to abandon our development efforts for such program or programs, which would harm our business. If we do not successfully develop and commercialize product candidates based upon our approach, we will not be able to obtain drug revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

We may fail to obtain and maintain orphan drug designations from the FDA for our current and future product candidates, as applicable. Even for ALLN-177 for which we have received such designation for treatment of primary hyperoxaluria and pediatric hyperoxaluria, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Our strategy includes filing for orphan drug designation where available for our product candidates. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full new drug application, or NDA, or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the original manufacturer is unable to assure sufficient product quantity.

The FDA has granted separate orphan drug designations for ALLN-177 for treatment of primary hyperoxaluria and for the treatment of pediatric hyperoxaluria. In addition, the European Commission has granted orphan designation for ALLN-177 for the treatment of primary hyperoxaluria. Even where we have obtained such designations, we may not be the first to obtain regulatory approval of a product candidate for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. We may also fail to meet requirements to maintain orphan drug designation during our continued development of ALLN-177, which is primarily focused on enteric hyperoxaluria. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the orphan-designated disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may

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receive and be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek orphan drug designation for our product candidates, we may never receive such designations.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties, including criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any drugs on the market, once we begin commercializing our product candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states, foreign governments and other jurisdictions in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal civil False Claims Act imposes criminal and civil penalties and authorizes civil whistleblower or qui tam actions against individuals or entities for: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; or making a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal physician payment transparency requirements, sometimes referred to as the “Sunshine Act” under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, require manufacturers of drugs,

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devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Department of Health and Human Services information related to physician payments and other transfers of value and the ownership and investment interests of such physicians and their immediate family members;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any of these occurrences may significantly harm our business, financial condition, prospects and results of operations and adversely affect our stock price.

Legislative or regulatory reform of the health care system in the United States and foreign jurisdictions may adversely impact our business, operations or financial results.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. In particular, in March 2010, the Affordable Care Act and a related reconciliation bill were signed into law. This legislation changes the current system of healthcare insurance and benefits intended to broaden coverage and control costs. The law also contains provisions that will affect companies in the pharmaceutical industry and other healthcare related industries by imposing additional costs and changes to business practices. Provisions affecting pharmaceutical companies include the following:

- mandatory rebates for drugs sold into the Medicaid program have been increased, and the rebate requirement has been extended to drugs used in risk-based Medicaid managed care plans;
- the definition of "average manufacturer price" was revised for reporting purposes, which could increase the amount of Medicaid drug rebates by state;
- the 340B Drug Pricing Program under the Public Health Service Act has been extended to require mandatory discounts for drug products sold to certain critical access hospitals, cancer hospitals and other covered entities;

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- pharmaceutical companies are required to offer discounts on brand-name drugs to patients who fall within the Medicare Part D coverage gap, commonly referred to as the "donut hole"; and
- pharmaceutical companies are required to pay an annual non-tax deductible fee to the federal government based on each company's market share of prior year total sales of branded products to certain federal healthcare programs. Since we expect our branded pharmaceutical sales to constitute a small portion of the total federal health program pharmaceutical market, we do not expect this annual assessment to have a material impact on our financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, which will remain in effect until 2024 unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

In addition, in September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted giving the FDA enhanced post-marketing authority including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to ensure compliance with post-approval regulatory requirements and potential restrictions on the sale and/or distribution of approved products. Other legislative and regulatory initiatives have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. For example, the Drug Supply Chain Security Act of 2013 imposes new obligations on manufacturers of certain pharmaceutical products related to product tracking and tracing. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance documents or interpretations will be changed, or what the impact of such changes on the marketing approvals of ALLN-177, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the Affordable Care Act. In May 2017, the House of Representatives passed legislation to repeal and replace parts of the Affordable Care Act. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Thus, the full impact of the Affordable Care Act, any law repealing and/or replacing elements of it, and the political uncertainty surrounding any repeal or replacement legislation on our business remains unclear.

Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future. Further, federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated

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revenues from ALLN-177 and any other product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

If successful product liability claims are brought against us, we may incur substantial liability and costs. If the use of our product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, participants in our clinical trials, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- increased FDA warnings on product labels;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We carry product liability insurance in amounts that we believe are sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our product candidates, if approved, or require us to suspend or abandon our commercialization efforts of any approved product candidates. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

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We depend heavily on the success of our most advanced program, ALLN-177. Our only other product development program, ALLN-346, is at the preclinical stage. Preclinical testing and clinical trials of product candidates may not be successful. If we are unable to commercialize any product candidates we may develop or experience significant delays in doing so, our business will be materially harmed.

We have invested substantially all of our efforts and financial resources in the identification and development of our most advanced product program, ALLN-177 for the treatment of hyperoxaluria. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of ALLN-177 and our future product candidates. The success of ALLN-177, ALLN-346 and future product candidates we may identify and develop will depend on many factors, including the following:

- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials for our most advanced program;
- successful completion of preclinical studies;
- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities in our target indications and potential additional indications;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our medicines;
- launching commercial sales of the medicines, if and when approved, whether alone or in collaboration with others;
- acceptance of the medicines, if and when approved, by patients, the medical community, and third-party payors;
- effectively competing with other therapies and treatment options;
- a continued acceptable safety profile of the medicines following approval;
- enforcing and defending intellectual property and proprietary rights and claims; and
- achieving desirable medicinal properties for the intended indications.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our most advanced program or any other product candidates we may develop, which would materially harm our business.

Of the large number of biologics and drugs in development in the pharmaceutical industry, only a small percentage result in the submission of a BLA or NDA to the FDA or an MAA to the EMA. Not all BLAs, NDAs or MAAs that are submitted to a regulatory agency are approved for commercialization. ALLN-177 is an oral biologic product candidate, which is a less common formulation in the biotech industry. Accordingly, there are few oral biologic therapeutics that have achieved regulatory approval. Furthermore, even if we do receive regulatory approval to market our most advanced program or any other product candidates that we may identify and develop, any such approval may be subject to limitations on the indicated uses for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our research programs, we cannot assure you that we will successfully develop or commercialize our most advanced program, or any of our other research programs. If we or any of our future development partners are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize, our most advanced program or any product candidates we may identify and develop, we may not be able to generate sufficient revenue to continue our business.

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Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulators. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. Although the incidences of adverse events that were considered related to study drug were low and no drug-related serious or severe adverse events were observed, it is possible that our planned Phase 3 program or future clinical trials we conduct may not demonstrate a favorable safety profile. In addition, while we have not observed ALLN-177 to be absorbed in our clinical trials to date, it is possible absorption could occur in our planned Phase 3 clinical trials, particularly with a target population of patients with enteric hyperoxaluria, who are predisposed to chronic hyperabsorption. We may also need to conduct additional clinical trials or other testing for, among other things, drug-drug interactions, the generation of formate and increased dosages of our product candidates. In the event of adverse safety issues, our trials could be suspended or terminated and the FDA or comparable foreign regulator could order us to cease further development of or deny approval of ALLN-177 for any or all targeted indications. Any drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If ALLN-177 or our other product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

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Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, and reimbursement for new medicines vary widely from country to country. Some countries require approval of the sale price of a medicine before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the medicine in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to commercialize any medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any medicine that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulators. Moreover, eligibility for reimbursement does not imply that any medicine will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, marketing and distribution. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the medicine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved medicines we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize medicines, and our overall financial condition.

Due to the novel nature of our product candidates and the potential for any product candidates we may develop to offer therapeutic benefit, we face uncertainty related to pricing and reimbursement for these product candidates.

Our initial target patient populations are relatively small, as a result of which the pricing and reimbursement of any product candidates we may develop, if approved, must be adequate to support the necessary commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any such product candidates will be adversely affected. The manner and level at which reimbursement is

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provided for services related to any product candidates we may develop (e.g. for administration of our product to patients) is also important. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our products. In addition, it may be necessary for us to develop new reimbursement models in order to realize adequate value. Payors may not be able or willing to adopt such new models, and patients may be unable to afford that portion of the cost that such models may require them to bear. If we determine such new models are necessary but we are unsuccessful in developing them, or if such models are not adopted by payors, our business, financial condition, results of operations, and prospects could be adversely affected.

We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford our product candidates. Accordingly, sales of any such product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of any product candidates we may develop will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers, and other third-party payors. Coverage and reimbursement by a third-party payor may depend upon several factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical, and cost-effectiveness data. There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any product candidates we may develop. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

Moreover, the downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products such as ours. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any product candidates we may develop will be harmed.

In light of the large population of patients with hyperoxaluria who reside outside the United States, our ability to generate meaningful revenues in those jurisdictions may be limited due to the strict price controls and reimbursement limitations imposed by governments outside of the United States.

In some countries, particularly those in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially, if we are not able to market our product to the large population of patients with hyperoxaluria who reside in outside the United States.

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Currently we plan to seek regulatory approval to market ALLN-177 solely for the treatment of enteric hyperoxaluria in adults and, unless we seek regulatory approval for additional indications, we will be prohibited from marketing ALLN-177 for any other indication.

We intend to initially seek approval to market ALLN-177 for the treatment of enteric hyperoxaluria in adults. Even if we obtain regulatory approval to market ALLN-177 in this indication, we will likely be prohibited from marketing ALLN-177 for any other indications. The FDA strictly regulates the promotional claims that may be made about prescription products. While ALLN-177 has been studied in patients beyond the enteric subgroup, ALLN-177 may not be promoted for uses that are not approved by the FDA as reflected in its approved labeling. Under applicable regulations, the ability of a company to make marketing statements about the effectiveness of its drug outside of the statements made in the label, referred to as "off-label" marketing, is prohibited. If we are found to have promoted such off-label uses, we may become subject to significant liability.

If we fail to comply or are found to have failed to comply with FDA and other regulations prohibiting the promotion of ALLN-177 for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations prohibiting the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other government agencies. If we receive marketing approval for ALLN-177 for the treatment of enteric hyperoxaluria in adults, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. We intend to implement compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of ALLN-177 for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

Over the past several years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Federal Food, Drug, and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "qui tam" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a qui tam suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

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Risks Related to Our Dependence on Third Parties

The third parties upon whom we rely for the supply of the drug product and drug substance used in our lead product candidate are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

We do not currently operate manufacturing facilities for clinical or commercial production of any product candidates. We have limited personnel experienced in drug manufacturing and formulation, and we lack the resources and the capabilities to manufacture ALLN-177 on a clinical or commercial scale. We do not intend to develop facilities for the manufacture of drug product candidates for clinical trials or products for commercial purposes in the foreseeable future. The drug product and drug substance used in ALLN-177 are supplied to us from single-source suppliers. Our ability to successfully develop our product candidates, to supply the drug required for our planned clinical trials, and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain the drug product and drug substance for these drugs in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We do not currently have arrangements in place for a redundant or second-source supply of any such drug product or drug substance in the event any of our current suppliers of such drug product and drug substance cease their operations for any reason.

For all of our product candidates, we intend to identify and qualify additional manufacturers to provide such drug product and drug substance prior to submission of a BLA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the drug product and drug substance used in our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. While we seek to maintain adequate inventory of the drug product and drug substance used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such drug product and drug substance from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

We plan to continue to rely upon contract manufacturers and, potentially, collaboration partners to manufacture commercial quantities of our product candidates if and when approved for marketing by the applicable regulatory authorities. We have not secured commercial supply agreements with any contract manufacturers for ALLN-177 and can give no assurance that we will enter commercial supply agreements with any contract manufacturers on favorable terms or at all or that we will be able to manufacture our product candidates at commercial scale at the cost we expect. Our contract manufacturers' failure to achieve and maintain high manufacturing standards, in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury or death, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

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An element of our strategy is to enter into licensing or collaboration agreements with respect to ALLN-177 and future product candidates in certain territories. We may not be able to identify suitable collaborators and, even if we do, our dependence on such relationships may adversely affect our business.

Because we have limited resources, we may seek to enter into collaboration agreements with other pharmaceutical or biotechnology companies. Our strategy for commercializing ALLN-177 and any future product candidates we may develop outside of the United States may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of our product candidates in the territories in which we may seek to partner. Despite our efforts, we may be unable to secure collaborative licensing or other arrangements that are necessary for us to further develop and commercialize our product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities ourselves, we may not be able to further develop our product candidates or bring them to market or continue to develop our technology platforms, and our business may be materially and adversely affected. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we may have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of any of our future program collaborators.

Any future collaborations that we enter into may not be successful. Any failure by our partners to perform their obligations or any decision by our partners to terminate these agreements could negatively impact our ability to successfully develop, obtain regulatory approvals for and commercialize our product candidates. In addition, partners may not properly obtain, maintain or, defend or enforce our intellectual property rights, may infringe, misappropriate or otherwise violate third-party intellectual property rights, may misappropriate our trade secrets or may otherwise use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation and potential liability. In the event we grant exclusive rights to such partners, we could be precluded from potential commercialization of our product candidates within the territories in which we have a partner. Furthermore, any termination of our collaboration agreements will terminate any funding we may receive under the relevant collaboration agreement and may impair our ability to fund further development efforts and our progress in our development programs.

Further, our potential future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our product candidates receive less attention or resources than we would like, or they may be terminated altogether. Any such actions by our potential future collaborators may harm our business prospects and ability to earn revenues. In addition, we could have disputes with our potential future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of our product candidates or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

We have relied, and will rely in the future, on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not appropriately carry out their contractual duties, fail to conduct high-quality studies or meet expected deadlines, regulatory approval and commercialization of ALLN-177 or any future candidates we may develop could be delayed or not obtained at all.

We do not have the ability to conduct all of our clinical trials independently. We have relied will continue to rely on third parties, including clinical investigators, third-party CROs, patients and consultants, to monitor, manage data for, participate in and execute our ongoing nonclinical and planned clinical programs for ALLN-177

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and other product candidates, and we control only some aspects of their activities. For example, in our completed Phase 2 clinical trials we relied heavily on the efforts and contributions of investigative clinical sites and study patients to comply with a strict treatment regimen (e.g. three capsules per day with meals) and accurate timing of 24 hour urine collection, with the complete collection of all of the patient's urine during a given 24 hour period and with the proper handling of collected urine specimens, including storage, documentation, sample handling and shipping to the testing laboratory. Any failure of these third parties to meet their obligations has had or may in the future have an adverse effect on the results of clinical trials we have conducted or will conduct.

Because we rely on third parties, our internal capacity to perform these functions is limited. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. Nevertheless, we are responsible for ensuring that each of our nonclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific requirements and standards, including, for example, GLP, the Animal Welfare Act and GCPs. Our reliance on third parties does not relieve us of our regulatory responsibilities. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the relevant regulatory authorities may require us to perform additional clinical trials in support of our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. We are also required to register clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to comply with these regulations may require us to repeat nonclinical studies and clinical trials, which would delay the regulatory approval process.

The third parties conducting our nonclinical studies and clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing clinical and nonclinical programs. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our nonclinical studies and clinical trials may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, regulatory approval of or successfully commercialize ALLN-177 and any other product candidates we may develop. As a result, our results of operations and the commercial prospects for our product candidates could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture ALLN-177 and conduct other aspects of our clinical development activities, we must, at times, share trade secrets and other confidential information with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with any collaborators, CROs, manufacturers and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or other confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets and confidential information become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's or other third party's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

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In addition, these agreements typically restrict the ability of certain collaborators, CROs, manufacturers and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. Despite our efforts to protect our trade secrets, our competitors or other third parties may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. Discovery of our trade secrets by a competitor or other third party would impair our competitive position and have an adverse impact on our business.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception, expect to incur significant and increasing losses for at least the next several years, have not generated any revenue, may never generate any revenue, and may never achieve or maintain profitability.

We have incurred significant annual net operating losses in every year since our inception. We expect to continue to incur significant and increasing net operating losses for at least the next several years. Our net losses were $14.2 million and $24.5 million for the years ended December 31, 2015 and 2016, respectively, and $10.3 million for the six months ended June 30, 2017. As of June 30, 2017, we had an accumulated deficit of $70.6 million. We have not generated any revenue, have not completed the development of any product candidate and may never have a product candidate approved for commercialization. We have financed our operations to date through $96.0 million in gross proceeds from private placements of our preferred stock and $10.0 million in gross proceeds from our credit facility with Silicon Valley Bank, or SVB. We have devoted substantially all of our financial resources and efforts to research and development of ALLN-177 and general and administrative expense to support such research and development. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' (deficit) equity and working capital.

We anticipate that our expenses will increase substantially if and as we:

- conduct future clinical trials of our lead product candidate, ALLN-177, including our planned pivotal Phase 3 clinical program in adult patients with enteric hyperoxaluria;
- manufacture additional material for these potential future clinical trials;
- scale up our manufacturing process for ALLN-177 to prepare for the submission of a potential BLA and commercialization if our clinical development program is successful;
- advance the development of ALLN-346;
- seek to identify and develop additional product candidates;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various products for which we may obtain marketing approval, if any;
- obtain, maintain, expand and protect our intellectual property portfolio;
- hire and retain additional personnel, such as clinical, manufacturing, quality control and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company; and
- add equipment and physical infrastructure to support our research and development programs.

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Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we are, or any future collaborator is, able to obtain marketing approval for, and successfully commercialize, one or more of our product candidates. Successful commercialization will require achievement of key milestones, including initiating and successfully completing clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, if any, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations and cause a decline in the value of our stock price.

We have a limited operating history, no products approved for sale and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We commenced operations in 2011. Our operations to date have been limited to financing and staffing our company and developing our product candidates. We have not yet demonstrated an ability to obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Even if we consummate this offering, we will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.

Since our inception, most of our resources have been dedicated to the nonclinical and clinical development of our lead product candidate, ALLN-177. As of June 30, 2017, we had working capital of $34.1 million and capital resources consisting of cash, cash equivalents and short-term investments of $38.0 million. We believe that we will continue to expend substantial resources for the foreseeable future as we continue clinical development, seek regulatory approval, and prepare for the commercialization of ALLN-177 and develop ALLN-346 and any other product candidates we may choose to pursue. These expenditures will include costs associated with research and development, conducting nonclinical studies and clinical trials, obtaining regulatory approvals, sales and marketing, and manufacturing and supply. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial and/or regulatory approval process is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of ALLN-177 and any future product candidates.

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We believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, will allow us to fund our operating plan into 2020. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity, debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future funding requirements will depend on many factors, including, but not limited to:

- the time and cost necessary to complete our pivotal Phase 3 program and obtain regulatory approvals for ALLN-177 and the costs of post-marketing studies that could be required by regulatory authorities;
- the costs of manufacturing clinical trial supplies of ALLN-177;
- our ability to successfully commercialize ALLN-177;
- the selling and marketing costs associated with ALLN-177, including the cost and timing of building our sales and marketing capabilities;
- the amount of sales and other revenues from ALLN-177, including the sales price and the availability of adequate third-party reimbursement;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the progress, timing, scope and costs of our nonclinical studies and clinical trials, including the ability to enroll patients in a timely manner for potential future clinical trials;
- our ability to comply with the covenants under our current and future credit facilities;
- the time and cost necessary to respond to technological and market developments; and
- the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate:

- clinical trials or other development activities for ALLN-177 or any other product candidate;
- our preclinical research and development activities; or
- our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize ALLN-177 or any future product candidate.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, our existing stockholders' ownership interest may be substantially diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. Additional debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. For example, our

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credit facility with Silicon Valley Bank, or SVB, contains restrictive covenants that, among other things and subject to certain exceptions, prohibit us from transferring any of our material assets, exclusively licensing our intellectual property (subject to certain exceptions), merging with or acquiring another entity, entering into a transaction that would result in a change of control, incurring additional indebtedness, creating any lien on our property, making investments in third parties or redeeming stock or paying dividends. Future debt securities or other financing arrangements could contain similar or more restrictive negative covenants. In addition, securing additional financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our existing and any future indebtedness could adversely affect our ability to operate our business.

As of June 30, 2017, we had $10.0 million of outstanding borrowings under our credit facility with SVB. We currently make monthly interest payments and, beginning in December 2017, will be required to repay principal and interest on these borrowings in monthly installments through May 2020. Subject to the restrictions in this existing credit facility, we could in the future incur additional indebtedness beyond our borrowings from SVB.

Our outstanding indebtedness, including any additional indebtedness beyond our borrowings from SVB, combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents. However, we may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under our existing credit facility or any other debt instruments. Failure to make payments or comply with other covenants under our existing credit facility or such other debt instruments could result in an event of default and acceleration of amounts due. Under our loan and security agreement with SVB, the occurrence of an event that would reasonably be expected to have a material adverse effect on our business, operations, assets or condition is an event of default. If an event of default occurs and SVB accelerates the amounts due, we may not be able to make accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness, which includes substantially all of our assets other than our intellectual property. In addition, the covenants under our existing credit facility, the pledge of our assets as collateral and the negative pledge with respect to our intellectual property could limit our ability to obtain additional debt financing.

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Risks Related to Our Business and Industry

We depend on the knowledge and skill of our senior management and other key employees, and if we are unable to retain or if we fail to recruit additional highly skilled personnel, our business will be harmed.

Our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract and retain highly qualified managerial, commercial, scientific and medical personnel. We are highly dependent on our management, commercial, scientific and medical personnel. In order to induce valuable employees to remain with us, we have provided employees with stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that we cannot control and, together with our other compensation programs and benefits, may at any time be insufficient to counteract more lucrative offers from other companies.

We are highly dependent upon the principal members of our management team, including Alexey Margolin, Ph.D., our Chief Executive Officer, Louis Brenner, M.D., our President and Chief Operating Officer, and Edward Wholihan, our Chief Financial Officer. The loss of any executive or other principal member of our management team would impair our ability to identify, develop and market new products and conduct successful operations.

In addition, our growth will require us to hire a significant number of qualified technical, commercial and administrative personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. Other biopharmaceutical companies with which we compete for qualified personnel may have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize ALLN-177 and any other product candidates we may develop would be impaired and could adversely affect our growth and financial performance.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other comparable foreign regulators, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We intend to adopt, prior to the completion of this offering, a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines,

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possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

In connection with this offering, we will adopt a Code of Business Conduct and Ethics, which will be effective upon the completion of this offering, and expect to prepare and implement policies and procedures to ensure compliance with such code. The Code of Business Conduct and Ethics mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, we cannot assure you that our employees and third-party intermediaries will comply with this code or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic

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tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Our business and operations would suffer in the event of computer system failures, cyber-attacks on our systems or deficiency in our cyber security.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, our systems safeguard important confidential personal data regarding patients enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in our operations, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of ALLN-177 and any other product candidates we may develop could be delayed.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient patent protection for our product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to commercialize our product candidates successfully may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary product candidates. If we do not adequately protect or enforce our intellectual property, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business. The patent application and approval process is expensive, complex and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to biological and pharmaceutical products commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

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Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in post-grant review procedures, oppositions, derivations, reexaminations, *inter partes* review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Our pending and future patent applications may not result in patents being issued which protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products, for example, ALLN-177. Alternatively, our competitors may seek to market generic versions of any approved products by submitting abbreviated BLAs to the FDA during which process they may claim that patents owned or licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We heavily rely on certain in-licensed patents and other intellectual property rights in connection with our development of ALLN-177 and, if we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

Our ability to develop and commercialize our lead product candidate, ALLN-177, is heavily dependent on licenses to patent rights and other intellectual property granted to us by third parties. For example, we are party to a license agreement with Althea Technologies, Inc. (now known as Ajinomoto Althea, Inc.), or Althea, under which we received an exclusive, worldwide, royalty-bearing, sublicensable, and, except under certain circumstances, non-transferable license under certain of the patent rights to develop, use, make, have made, market, offer to sell, sell, have sold, distribute, import or otherwise exploit ALLN-177 (see corresponding agreement summary in "Business—Althea License Agreement"). We may enter into additional license agreements in the future. Our license agreement with Althea imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under these licenses, our licensors, including Althea, may have the right to terminate these license agreements, in which event we might not be able to market our lead product candidate,

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ALLN-177. Similarly, other licensors may convert an exclusive license to a non-exclusive license, which could adversely affect the value of a product candidate developed under a given license agreement. Termination of any of our license agreements or reduction or elimination of our licensed rights may also result in our having to negotiate new or reinstated licenses with less favorable terms.

Further, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. For example, pursuant to our license agreement with Althea, Althea controls such activities for certain patents licensed to us under such agreement. Therefore, we cannot be certain that these patents will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our current or future licensors or collaboration partners fail to obtain, maintain or protect any patents or patent applications licensed to us, our rights to such patents and patent applications may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected.

Patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product's approval by the FDA, only one patent applicable to an approved drug is eligible for the extension, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. In the future, if and when our product candidates, for example, ALLN-177, receive FDA approval, we intend to apply for patent term extensions on patents covering those products in any jurisdiction where these are available. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. Moreover, we may not receive an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management, business and scientific personnel. In addition, many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

A court may disagree with our allegations and may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the third-party technology in question. Furthermore, the other party could counterclaim that we infringe their intellectual property or counterclaim that a patent we have asserted against them is invalid or unenforceable, or both. In patent litigation in the United States, counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. Similarly, third parties may initiate legal proceedings against us seeking a declaration that certain of our intellectual property rights are non-infringed, invalid, or unenforceable. The outcome of any such proceeding is generally unpredictable.

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Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, or written description. In addition, validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting and associated rules related to common ownership, which, if successful, could result in a finding that the patent claims at issue are invalid and unenforceable or a loss of patent term, including a patent term adjustment granted by the USPTO. Furthermore, patents may be held unenforceable if someone connected with prosecution of the patent in question withheld relevant information from the USPTO or made a misleading statement during prosecution of the patent. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. It is also possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid.

An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our product candidates, we would lose at least part, and perhaps all, of the patent protection covering such product candidate. Competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our drugs in one or more foreign countries. Any of these outcomes would have a material adverse effect on our business.

Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearing, motions, or other interim developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Even if we ultimately prevail, a court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Furthermore, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business.

We may not be able to effectively enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the patent laws of some foreign countries do not afford intellectual property protection to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, for example, India and China, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, certain foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in the major markets for our product candidates, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our drugs or procedures, we may not be able to stop a competitor from marketing drugs that are the same as or similar to our product candidates, which would have a material adverse effect on our business.

If we are sued for infringing intellectual property of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights and intellectual property of third parties. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technologies we use in our business. Our competitors or other third parties may assert infringement claims against us, alleging that our product candidates are covered by their patents. We cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. For example, we are aware of companies that have filed patent applications directed to oxalate and uric acid degrading enzymes, some of which have already been allowed or issued, and others may issue in the future. It is possible that additional patent applications are filed and additional patents directed to these enzymes are granted in the future. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. If a patent holder believes our product candidate infringes its patent rights, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect.

If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable. However, proving invalidity and unenforceability is difficult. In the United States, for example, providing invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

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If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our product candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby providing our competitors and other third parties access to the same technologies licensed to us. Without such a license, we could be forced, including by court order, to cease developing and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed such third-party patent rights. A finding of infringement could significantly harm our business and operating results.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnological and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnological and pharmaceutical industries involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first to file" system. The first-to-file provisions, however, only became effective on March 16, 2013. It is still not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

Although we have obtained composition of matter patents covering ALLN-177 and its use in therapy, we also rely on trade secrets, including confidential and unpatented know-how important to the maintenance of our competitive position. We protect our trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, outside scientific collaborators, advisors, contractors, contract manufacturers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or

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independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

We may be subject to claims by third parties asserting that our employees or we have misappropriated or otherwise violated their intellectual property rights, or claiming ownership of what we regard as our own intellectual property.

Many of our consultants, advisors and employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies. Some of these individuals, including certain members of our senior management, may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our consultants, advisors and employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Our Common Stock and this Offering

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for

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us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We are currently evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or SOX Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the Securities and Exchange Commission, or the SEC, after we become a public company. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by SOX Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

Our stock price is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your shares of our common stock at or above the initial public offering price and you may lose some or all of your investment. The market price for our common stock may be influenced by many factors, including:

- the success of competitive drugs or technologies;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures,
- collaborations or capital commitments;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts, and our performance in relation to such estimates;
- variations in our financial results or those of companies that are perceived to be similar to us;
- announcement or expectation of additional financing efforts;

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- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

An active trading market for our common stock may not develop, and you may not be able to resell your shares of our common stock at or above the initial public offering price, if at all, and our ability to raise capital in the future may be impaired.

Prior to this offering, there has been no public market for shares of our common stock. Although our common stock is listed on The Nasdaq Stock Market, an active trading market for our shares may never develop or be sustained following this offering. The initial public offering price of our common stock was determined through negotiations between us and the underwriters. This initial public offering price may not be indicative of the market price of our common stock after this offering. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the initial public offering price or at the time that they would like to sell, if at all, and our ability to raise capital in the future may be impaired.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock will likely depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us, or provide favorable coverage. If one or more analysts downgrade our stock or change their opinion of our stock, our share price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Our directors, executive officers and principal stockholders exercise significant control over our company, which will limit your ability to influence corporate matters.

As of June 30, 2017, our executive officers, directors and principal stockholders collectively controlled approximately 91.7% of our outstanding common stock, excluding any shares of common stock that such persons may have the right to acquire upon exercise of outstanding options or warrants. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. Certain of our existing stockholders, including certain affiliates of our directors, have agreed to participate in this offering by purchasing shares of our common stock in this offering at the initial public offering price. If such stockholders purchase all shares they have agreed to purchase, our executive officers, directors and principal stockholders will collectively control approximately 84.6% of our outstanding common stock following this offering. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions.

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Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and amended and restated by-laws may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is otherwise doing well.

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market after the 180-day contractual lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline significantly and could decline below the initial public offering price. Based on shares outstanding as of June 30, 2017, upon the completion of this offering, we will have 20,621,848 outstanding shares of common stock, assuming no exercise of outstanding options or warrants. Of these shares, assuming no shares are purchased in this offering by our existing stockholders, all of the shares of common stock sold in this offering, plus any shares sold pursuant to the underwriters' option to purchase an additional shares, will be immediately freely tradable, without restriction, in the public market.

After the lock-up agreements pertaining to this offering expire, an additional 15,295,001 shares will be eligible for sale in the public market. In addition, the 1,394,299 shares subject to outstanding options under our stock option plans, the 2,038,021 shares reserved for future issuance under our stock option plans and the shares subject to outstanding warrants will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Moreover, 180 days after the completion of this offering, holders of approximately 13,945,509 shares of our common stock will have the right to require us to register these shares under the Securities Act of 1933, as amended, pursuant to an investors' rights agreement entered into prior to the completion of this offering. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

We will have broad discretion in the use of proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree or in ways that ultimately may not increase the value of your investment.

We will have broad discretion over the use of proceeds from this offering. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. We expect to use the net proceeds to us from this offering for our planned pivotal Phase 3 clinical program of ALLN-177 for the treatment of patients with enteric hyperoxaluria; for our planned Phase 2 clinical trial of ALLN-177 in adolescents and adults with primary hyperoxaluria or severe forms of secondary hyperoxaluria; for our planned development of ALLN-346 for the treatment of patients with hyperuricemia and CKD; to fund our process validation and

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manufacturing batches for ALLN-177; and the remainder for working capital and other general corporate purposes. Our failure to apply the net proceeds from this offering effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. In addition, the net proceeds from this offering may not be sufficient for our anticipated uses, and we may need additional resources to progress our product candidates to the stage we expect. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of SOX Section 404, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. In this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We do not intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so in the foreseeable future. Our credit facility with SVB also prohibits us from paying cash dividends without the prior written consent of SVB. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchased them.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in the ownership of its equity over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of this offering or subsequent shifts in our stock ownership, some of which are outside our control. As of

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December 31, 2016, we had federal net operating loss carryforwards of approximately $58.8 million, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to us.

Volatility in our share price could subject us to securities class action litigation.

Securities class action litigations have often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If you purchase shares of common stock in this offering, you will suffer immediate dilution in the net tangible book value of your investment.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. Therefore, purchasers of shares of our common stock in this offering will pay a price per share that substantially exceeds our net tangible book value per share after this offering. Based on the initial public offering price of $14.00 per share, you will experience immediate dilution of $9.49 per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and the initial public offering price.

Purchasers of common stock in this offering will have contributed approximately 44% of the aggregate price paid by all purchasers of our stock and will own approximately 26% of our common stock outstanding after this offering, excluding any shares of our common stock that they may have acquired prior to this offering. Furthermore, if the underwriters exercise their option to purchase additional shares or our previously issued options to acquire common stock at prices below the initial public offering price are exercised, you will experience further dilution. For additional information on the dilution that you will experience immediately after this offering, see the section titled "Dilution."

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, would result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2017 Stock Option and Incentive Plan, or the 2017 Plan, which became effective upon the effectiveness of the registration statement of which this prospectus is a part, we are authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2017 Plan will automatically increase each year by up to 4% of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our board of directors or compensation committee to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2017 Plan each year. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, and our stock price may fall.

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As a public reporting company, we will be subject to rules and regulations established from time to time by the SEC and the Public Company Accounting Oversight Board, or PCAOB, regarding our internal control over financial reporting. We may not complete improvements to our internal control over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the market price of our common stock could decline and you could lose all or part of your investment.

Upon completion of this offering, we will become a public reporting company subject to the rules and regulations established from time to time by the SEC and the PCAOB. These rules and regulations will require, among other things, that we establish and periodically evaluate procedures with respect to our internal controls over financial reporting. Reporting obligations as a public company are likely to place a considerable strain on our financial and management systems, processes and controls, as well as on our personnel.

In addition, as a public company we will be required to document and test our internal controls over financial reporting pursuant to SOX Section 404, so that our management can certify as to the effectiveness of our internal controls over financial reporting by the time our annual report for the year ending December 31, 2018 is due and thereafter, which will require us to document and make significant changes to our internal controls over financial reporting. Likewise, our independent registered public accounting firm will be required to provide an attestation report on the effectiveness of our internal control over financial reporting at such time as we cease to be an "emerging growth company," as defined in the JOBS Act, although, as described in the preceding risk factor, we could potentially qualify as an "emerging growth company" for more than five years. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating.

If our senior management is unable to conclude that we have effective internal control over financial reporting, or to certify the effectiveness of such controls, or if our independent registered public accounting firm cannot render an unqualified opinion on management's assessment and the effectiveness of our internal control over financial reporting once we cease to be an emerging growth company, or if material weaknesses in our internal controls are identified, we could be subject to regulatory scrutiny and a loss of public confidence, which could have a material adverse effect on our business and our stock price. In addition, if we do not maintain adequate financial and management personnel, processes and controls, we may not be able to manage our business effectively or accurately report our financial performance on a timely basis, which could cause a decline in our common stock price and adversely affect our results of operations and financial condition.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to reasonably ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures as well as internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are and will be met. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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Our restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employee to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. These statements include all matters that are not related to present facts or current conditions or that are not historical facts, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth. The words "anticipate," "believe," "could," "continue," "should," "predict," "estimate," "expect," "intend," "may," "plan," "potentially," "will," "may," "would," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this prospectus, regarding, among other things:

- the design and conduct of our planned Phase 3 clinical program of ALLN-177 in enteric hyperoxaluria;
- the number, designs, results and timing of our clinical trials and preclinical studies and the timing of the availability of data from these trials and activities;
- our ability to enroll a sufficient number of patients and the ability of subjects in our clinical trials to adhere to the protocol, including capsule and dietary regimen and urinary collection requirements;
- the therapeutic benefits, effectiveness and safety of ALLN-177, ALLN-346 and our future product candidates;
- our ability to receive regulatory approval for our product candidates in the United States, Europe and other geographies;
- our ability to obtain, on satisfactory terms or at all, the financing required to support operations, development, clinical trials, and commercialization of products;
- our reliance on third-parties for the planning, conduct and monitoring of clinical trials and for the manufacture of clinical drug supplies and drug product;
- potential changes in regulatory requirements, and delays or negative outcomes from the regulatory approval process;
- our estimates of the size and characteristics of the markets that may be addressed by ALLN-177 and ALLN-346;
- the market acceptance of ALLN-177, ALLN-346 or any future product candidates that are approved for marketing in the United States or other countries;
- our ability to successfully commercialize ALLN-177 with a targeted sales force;
- the safety and efficacy of therapeutics marketed by our competitors that are targeted to indications which our product candidates have been developed to treat;
- our ability to utilize our proprietary technological approach to develop and commercialize ALLN-346 and future product candidates;
- potential collaborators to license and commercialize ALLN-177, if approved, or any products for which we receive regulatory approval in the future outside of the United States;
- our heavy dependence on licensed intellectual property, including our ability to source and maintain licenses from third-party owners;

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- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our ability to attract, retain and motivate key personnel;
- our ability to generate revenue and become profitable;
- our expectations related to the use of proceeds, if any, from this offering; and
- our estimates regarding our capital requirements and our need for additional financing.

These risks are not exhaustive. Other sections of this prospectus may include additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

We have included important factors in the cautionary statements included in this prospectus, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. No forward-looking statement is a guarantee of future performance.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

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INDUSTRY AND MARKET DATA

This prospectus includes statistical and other industry and market data that we obtained from our own internal estimates and research, as well as from industry publications and research, surveys and studies conducted by us and third parties. Industry publications, studies, and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that each of these studies and publications is reliable, we have not independently verified market and industry data from third-party sources. While we believe our internal company research is reliable and the market definitions are appropriate, neither such research nor these definitions have been verified by any independent source. The industry in which we operate is subject to a high degree of uncertainty and risks due to various factors, including those described in the section titled “Risk Factors.”

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USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of 5,333,333 shares of common stock in this offering will be approximately $66.4 million at the initial public offering price of $14.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that the net proceeds will be approximately $76.9 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We currently expect to use the net proceeds from this offering, together with our existing cash, cash equivalents and investments, as follows:

- approximately $45.0 million for our planned pivotal Phase 3 clinical program of ALLN-177 for the treatment of patients with enteric hyperoxaluria, including clinical research outsourcing and drug manufacturing;
- approximately $3.0 million for our planned Phase 2 clinical trial of ALLN-177 in adolescents and adults with primary hyperoxaluria or severe forms of secondary hyperoxaluria, including clinical research outsourcing and drug manufacturing;
- approximately $3.0 million for our planned development of ALLN-346 for the treatment of patients with hyperuricemia and CKD, including preclinical proof of concept in hyperuricemia animal models, customary toxicology studies and preparation for filing of an investigational new drug application;
- approximately $8.0 million to fund our process validation and manufacturing batches for ALLN-177; and
- the remainder for working capital and other general corporate purposes, which includes making scheduled principal and interest payments under our existing $10.0 million credit facility, funding for additional research, hiring additional personnel, capital expenditures and the costs of operating as a public company.

As of June 30, 2017, the outstanding principal balance of our credit facility was $10.0 million. The credit facility has an interest only period that expires in December 2017. Upon the expiration of the interest only period, the outstanding amounts will be repaid over 30 months in equal monthly principal payments plus monthly payments of accrued interest. The outstanding principal balance accrues interest at a floating per annum rate equal to the greater of 4.0% or 0.5% above the Prime Rate (as defined in the credit facility). At June 30, 2017, the interest rate was 4.75%. In addition, we are required to make a final payment equal to 8.25% of the original principal amount, which is due on the earliest to occur of (a) the loan maturity date, which is May 1, 2020, (b) upon an acceleration of the loan in accordance with the credit facility or (c) the prepayment of the then outstanding principal balance.

The expected use of the net proceeds from this offering represents our current intentions based upon our present plans and business conditions, which could change in the future as our plans and business conditions evolve. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amount and timing of our actual expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing of regulatory submissions and the feedback from regulatory authorities, the timing and success of our planned clinical trials, preclinical studies, or studies or trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs. Moreover, our estimates of the costs to fund our planned clinical trials are based on our expected designs of the trials. If the design of any of these trials were to be modified, for instance, to increase the number of patients in the trials, our costs to fund the trials could increase. As a result, our management will have broad discretion over the use of the net proceeds from this offering.

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Although we may use a portion of the net proceeds of this offering for the acquisition or licensing, as the case may be, of additional technologies, other assets or businesses, or for other strategic investments or opportunities, we have no current understandings, agreements, commitments or plans to do so.

Based on our planned use of the net proceeds from this offering and our existing cash, cash equivalents and investments, we estimate that such funds will be sufficient to enable us to fund our operating expenses, debt service, and capital expenditure requirements into 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Based on our current operating expectations, we estimate that we will have sufficient resources to complete (i) our two planned Phase 3 clinical trials of ALLN-177 in patients with enteric hyperoxaluria, (ii) our planned Phase 2 clinical trial of ALLN-177 in adolescents and adults with primary hyperoxaluria and other severe forms of hyperoxaluria and (iii) our planned proof of concept and customary preclinical toxicology studies of ALLN-346 and, subject to the successful outcome of these studies, the filing of our IND. We will need to raise additional proceeds to secure marketing approval and to fund the commercialization of ALLN-177 if marketing approval is obtained as well as continue the development of ALLN-177 in other indications and advance ALLN-346 into clinical development.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. With the exception of our credit facility, we do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of our common stockholders. Additional debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Pending the use of the proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, interest-bearing, investment-grade securities, certificates of deposit or government securities.

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DIVIDEND POLICY

We have never declared or paid any dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. In addition, pursuant to our loan and security agreement with SVB, we are prohibited from paying cash dividends without the prior written consent of SVB. Moreover, any future indebtedness that we may incur could preclude us from paying dividends. Any future determination to pay dividends will be made at the discretion of our board of directors. Investors should not purchase our common stock with the expectation of receiving cash dividends.

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CAPITALIZATION

The following table sets forth our cash and capitalization as of June 30, 2017 on:

- an actual basis;
- a pro forma basis to give effect to (i) the automatic conversion of all 58,208,614 outstanding shares of our preferred stock into an aggregate of 13,945,509 shares of common stock immediately prior to the closing of this offering; (ii) the filing of our restated certificate of incorporation immediately prior to the closing of this offering; and (iii) the automatic conversion of warrants to purchase preferred stock into warrants to purchase common stock resulting in the reclassification of our warrant liability to stockholders' equity; and
- a pro forma as adjusted basis to give further effect to the sale of 5,333,333 shares of our common stock offered in this offering at the initial public offering price of $14.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information together with our financial statements and related notes appearing elsewhere in this prospectus and the information set forth in the sections titled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of June 30, 2017		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share data)		
Cash, cash equivalents and investments	$ 37,962	$ 37,962	$ 104,402
Loan payable, net of discount	$ 9,641	$ 9,641	$ 9,641
Warrants for the purchase of shares subject to redemption	299	—	—
Series A convertible preferred stock, $0.001 par value; 18,510,200 shares authorized, 18,367,344 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	17,971	—	—
Series B convertible preferred stock, $0.001 par value; 19,841,270 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	24,939	—	—
Series C convertible preferred stock, $0.001 par value; 20,037,736 shares authorized, 20,000,000 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	52,851	—	—
Stockholders' (deficit) equity:			
Preferred stock, $0.001 par value; no shares authorized, issued or outstanding, actual; 5,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.001 par value; 75,000,000 shares authorized, 1,343,006 shares issued and outstanding, actual; 125,000,000 shares authorized, 15,288,515 shares issued and outstanding, pro forma; 125,000,000 shares authorized, 20,621,848 shares issued and outstanding, pro forma as adjusted	1	15	21
Additional paid-in capital	1,195	97,241	163,675
Accumulated deficit	(70,610)	(70,610)	(70,610)
Total stockholders' (deficit) equity	(69,414)	26,646	93,086
Total capitalization	$ 36,287	$ 36,287	$ 102,727

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The actual, pro forma and pro forma as adjusted information set forth in the table above excludes the following:

- 1,394,299 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2017 at a weighted-average exercise price of $1.41 per share;
- 43,265 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2017 at a weighted-average exercise price of $5.55 per share;
- 734,590 shares of common stock reserved for future issuance under our 2011 Stock Incentive Plan, or the 2011 Plan, as of June 30, 2017 which, upon the effectiveness of the registration statement of which this prospectus forms a part, became reserved for future issuance under our 2017 Stock Option and Incentive Plan, or the 2017 Plan, as reflected below;
- 2,038,021 shares of common stock reserved for future issuance under our 2017 Plan; and
- 206,284 shares of common stock reserved for the future issuance under our 2017 Employee Stock Purchase Plan.

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DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

We had a net tangible book value (deficit) of $(69.4) million, or $(51.69) per share of common stock, as of June 30, 2017. Our net tangible book value represents total tangible assets less total liabilities and convertible preferred stock. Our net tangible book value per share is our net tangible book value divided by the number of shares of our common stock outstanding as of June 30, 2017.

The pro forma net tangible book value of our common stock as of June 30, 2017 was $26.6 million, or $1.74 per share of our common stock. Pro forma net tangible book value per share represents the amount of our total tangible assets less our total liabilities, divided by the pro forma number of shares of our common stock outstanding after giving effect to (1) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 13,945,509 shares of common stock upon the closing of this offering, and (2) the automatic conversion of warrants to purchase preferred stock into warrants to purchase common stock resulting in the reclassification of our warrant liability to stockholders' equity.

After giving further effect to the sale of 5,333,333 shares of common stock in this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, at the initial public offering price of $14.00 per share, our pro forma as adjusted net tangible book value as of June 30, 2017 would have been $93.1 million, or $4.51 per share of common stock. This represents an immediate increase in pro forma net tangible book value of $2.77 per share to our existing stockholders and an immediate dilution of $9.49 per share to investors participating in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$14.00
Historical net tangible book value (deficit) per share as of June 30, 2017	$(51.69)	
Pro forma increase in net tangible book value per share attributable to the conversion of outstanding preferred stock and warrants to purchase preferred stock	53.43	
Pro forma net tangible book value per share as of June 30, 2017	1.74	
Pro forma increase in net tangible book value per share attributable to this offering	2.77	
Pro forma as adjusted net tangible book value per share, after giving effect to this offering		4.51
Dilution of pro forma as adjusted net tangible book value per share to new investors		$ 9.49

If the underwriters exercise their option to purchase additional shares in full, pro forma as adjusted net tangible book value as of June 30, 2017 will increase to $103.5 million, or $4.83 per share, representing an increase to existing stockholders of $0.32 per share, and there will be an immediate dilution of $9.17 per share to new investors, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, on a pro forma as adjusted basis as of June 30, 2017, the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid by existing stockholders (giving effect to the conversion of all outstanding shares of our preferred stock into 13,945,509 shares of common stock upon the completion of this offering) and by investors participating in this offering, before deducting underwriting discounts and commissions and estimated offering expenses, at the initial public offering price of $14.00 per share. As the table illustrates, new investors purchasing shares in this offering will pay an average price per share substantially higher than our existing stockholders paid.

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Certain of our existing stockholders who previously indicated an interest in purchasing shares of our common stock in this offering, including certain affiliates of our directors, have agreed to purchase an aggregate of approximately $20 million of shares of our common stock in this offering at the initial public offering price. The following table does not reflect the purchases by such stockholders in this offering.

	Shares Purchased		Total Consideration		Average Price
	Number	Percent	Amount	Percent	Per share
			(in thousands)		
Existing stockholders	15,288,515	74%	$ 96,043	56%	$ 6.28
IPO investors	5,333,333	26%	74,667	44%	14.00
Total	20,621,848	100%	$170,710	100%	

If the underwriters exercise their option to purchase additional shares in full, our existing stockholders would own 71% and our new investors would own 29% of the total number of shares of common stock outstanding after the closing of this offering.

The number of shares of common stock to be outstanding after this offering is based on 15,288,515 shares of our common stock outstanding as of June 30, 2017, after giving effect to the conversion of all outstanding shares of our preferred stock as of June 30, 2017 into an aggregate of 13,945,509 shares of common stock upon the completion of this offering and excludes the following:

- 1,394,299 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2017 at a weighted-average exercise price of $1.41 per share;
- 43,265 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2017 at a weighted-average exercise price of $5.55 per share;
- 734,590 shares of common stock reserved for future issuance under our 2011 Plan as of June 30, 2017 which, upon the effectiveness of the registration statement of which this prospectus forms a part, became reserved for future issuance under our 2017 Stock Option and Incentive Plan, or the 2017 Plan, as reflected below;
- 2,038,021 shares of common stock reserved for future issuance under our 2017 Plan; and
- 206,284 shares of common stock reserved for the future issuance under our 2017 Employee Stock Purchase Plan.

New investors will experience further dilution if any of our outstanding options or warrants are exercised, new options are issued and exercised under our equity incentive plans or we issue additional shares of common stock, other equity securities or convertible debt securities in the future.

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SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the information under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The selected consolidated financial data in this section are not intended to replace the consolidated financial statements and are qualified in their entirety by the consolidated financial statements and related notes included elsewhere in this prospectus. We have derived the consolidated statements of operations data for the years ended December 31, 2015 and 2016 and the balance sheet data as of December 31, 2015 and 2016 from our audited consolidated financial statements included elsewhere in this prospectus. The selected consolidated financial data as of June 30, 2017 and for the six months ended June 30, 2016 and 2017 has been derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus. In the opinion of management, the unaudited condensed consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements and contain all adjustments, consisting of only normal recurring adjustments, that management considers necessary for the fair presentation of the financial information set forth in those statements. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period and our operating results for the six-month period ended June 30, 2017 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2017 or any other interim periods or any future year or period.

	Years Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
	(in thousands, except share and per share data)			
Consolidated Statement of Operations Data:				
Operating expenses:				
Research and development	$ 11,540	$ 20,103	$ 10,025	$ 7,809
General and administrative	2,365	4,083	2,057	2,208
Total operating expenses	13,905	24,186	12,082	10,017
Other income (expense):				
Interest income (expense), net	(335)	(200)	(71)	(255)
Other income (expense), net	(7)	(121)	1	(31)
Other income (expense), net	(342)	(321)	(70)	(286)
Net loss	$ (14,247)	$ (24,507)	$ (12,152)	$ (10,303)
Net loss per share attributable to common stockholders—basic and diluted(1)	$ (11.35)	$ (18.35)	$ (9.11)	$ (7.70)
Weighted-average common shares outstanding—basic and diluted(1)	1,258,123	1,339,254	1,337,100	1,342,628
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)(1)		$ (1.59)		$ (0.67)
Pro forma weighted-average common shares outstanding—basic and diluted (unaudited)(1)		15,284,763		15,288,137

(1) See Note 2 to our consolidated financial statements included elsewhere in this prospectus for a description of the method used to calculate basic and diluted net loss per share and unaudited pro forma basic and diluted net loss per share as well as the weighted-average number of common shares used in the calculation of the per share amounts.

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	December 31, 2015	December 31, 2016	June 30, 2017
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash, cash equivalents and investments	$ 69,011	$ 48,755	$ 37,962
Working capital(1)	64,735	46,025	34,142
Total assets	70,008	49,479	38,579
Loan payable, net of current portion and discount	3,932	9,409	7,553
Convertible preferred stock	95,658	95,727	95,761
Total stockholders' deficit	(34,969)	(59,277)	(69,414)

(1) We define working capital as current assets less current liabilities. See our consolidated financial statements for further details regarding our current assets and current liabilities.

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MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the "Selected Consolidated Financial Data" section of this prospectus and our consolidated financial statements and the related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a late-stage clinical biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders. We are focused on metabolic disorders that result in excess accumulation of certain metabolites that can cause kidney stones, damage the kidney, and potentially lead to chronic kidney disease, or CKD, and end-stage renal disease. Our lead product candidate, ALLN-177, is a first-in-class, oral enzyme therapeutic that we are developing for the treatment of hyperoxaluria, a metabolic disorder characterized by markedly elevated urinary oxalate levels and commonly associated with kidney stones, CKD and other serious kidney diseases. There are currently no approved therapies for the treatment of hyperoxaluria. We have conducted a robust clinical development program of ALLN-177, including three Phase 2 clinical trials, and we expect to initiate the first of two planned pivotal Phase 3 clinical trials for ALLN-177 in the first quarter of 2018, with topline data anticipated in the second half of 2019.

We were incorporated under the laws of the State of Delaware on June 24, 2011 and our headquarters is in Newton, Massachusetts. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential product candidates, producing drug substance and drug product material for use in preclinical studies and clinical trials, conducting preclinical studies of our product candidates and clinical trials for our lead product candidate, ALLN-177. We do not have any products approved for sale and have not generated any revenue to date. We have financed our operations to date primarily through private placements of convertible preferred stock and a credit facility with Silicon Valley Bank, or SVB. From inception through June 30, 2107, we have raised an aggregate of $106.0 million to fund our operations, of which $96.0 million were gross proceeds from sales of our convertible preferred stock and $10.0 million were the gross proceeds from our credit facility. As of June 30, 2017, we had cash, cash equivalents and investments totaling $38.0 million.

We have incurred significant net operating losses in every year since our inception and expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. Our net losses were $14.2 million and $24.5 million for the years ended December 31, 2015 and 2016, respectively, and $12.2 million and $10.3 million for the six months ended June 30, 2016 and 2017, respectively. As of June 30, 2017, we had an accumulated deficit of $70.6 million. We anticipate that our expenses will increase significantly as we:

- conduct future clinical trials of our lead product candidate, ALLN-177;
- manufacture additional material for our planned pivotal Phase 3 clinical program, planned Phase 2 clinical basket trial and potential future clinical studies we might conduct for our product candidates;
- scale up our manufacturing process for ALLN-177 to prepare for the filing of a potential biologics license application, or BLA, and commercialization if our clinical development program is successful;
- advance the development of ALLN-346;

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- seek regulatory and marketing approvals for product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval in geographies in which we plan to commercialize our products ourselves;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific, technical, operational, and financial personnel, to execute our business plan; and
- add clinical, scientific, operational, financial and management information systems to support our product development and potential future commercialization efforts, and to enable us to operate as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for a product candidate. Additionally, we currently use contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, to carry out our preclinical and clinical development activities. We do not yet have a sales organization. If we obtain regulatory approval for our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, commencing upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we may seek to fund our operations through public or private equity or debt financings or other sources, including strategic collaborations. We may, however, be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our current product candidates, or any additional product candidates, if developed.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales or any other source and do not expect to generate any revenue from the sale of products for the foreseeable future. If our development efforts for ALLN-177 or other product candidates that we may develop in the future are successful and result in marketing approval or collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts and the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits and stock-based compensation expense;
- costs incurred under agreements with third parties, including CROs, that conduct research and development, preclinical studies and clinical trials on our behalf;
- costs related to production of preclinical and clinical materials, including fees paid to CMOs;
- consulting, licensing and professional fees related to research and development activities;
- costs of purchasing laboratory supplies and non-capital equipment used in our preclinical activities;
- costs related to compliance with clinical regulatory requirements; and
- facility costs and other allocated expenses, which include expenses for rent and maintenance of facilities, insurance, depreciation and other supplies.

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We expense research and development costs as incurred. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as clinical site activations, patient enrollment, or information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and may be reflected in our consolidated financial statements as prepaid or accrued research and development expenses. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized, even when there is no alternative future use for the research and development. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

The following summarizes our most advanced current research and development programs:

- ALLN-177 is our lead product candidate which we are developing for the treatment of hyperoxaluria. Substantially all of our research and development costs to date have been used to fund this program.
- ALLN-346 is our second product candidate which we are developing for patients with hyperuricemia and CKD. We began incurring external research and development costs for this program in 2016.

We typically use our employee and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs and other internal costs to specific product candidates or development programs.

The following table summarizes our research and development expenses by program (in thousands):

	Years Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
ALLN-177 external costs	$ 9,059	$16,057	$ 8,579	$5,168
ALLN-346 external costs	—	312	—	123
Employee compensation and benefits	2,018	3,074	1,194	2,081
Other	463	660	252	437
Total research and development expenses	$11,540	$20,103	$10,025	$7,809

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages, primarily due to the increased size and duration of later-stage clinical trials. Since inception, we have incurred $44.8 million of external research and development costs for ALLN-177. We expect that our research and development costs will continue to increase for the foreseeable future as we initiate additional clinical trials of ALLN-177, scale our manufacturing processes and advance development of ALLN-346.

The successful development of ALLN-177, ALLN-346 and other potential future product candidates is highly uncertain. Accordingly, at this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of these product candidates. We are also unable to predict when, if ever, we will generate revenue and material net cash inflows from the commercialization and sale of any of our product candidates for which we may obtain marketing approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of preclinical studies, clinical trials and development of our product candidates will depend on a variety of factors, including:

- successful enrollment in, and completion of, clinical trials for ALLN-177;
- successful data from our clinical program of ALLN-177 that supports an acceptable benefit-risk profile of ALLN-177 in the intended populations;
- establishing an appropriate safety profile for ALLN-346 and any potential future product candidate with studies to enable the filing of an investigational new drug application;

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- approval of INDs for ALLN-346 and any potential future product candidate to commence planned or future clinical trials;
- significant and changing government regulation and regulatory guidance;
- timing and receipt of marketing approvals from applicable regulatory authorities;
- making arrangements with CMOs for third-party commercial manufacturing of our product candidates;
- obtaining and maintaining patent and other intellectual property protection and regulatory exclusivity for our product candidates;
- commercializing the product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of the product, if and when approved, by patients, the medical community and third-party payors; and
- maintenance of a continued acceptable safety profile of the drugs following approval.

A change in the outcome of any of these variables with respect to the development, manufacture or commercialization enabling activities of any of our product candidates could mean a significant change in the costs, timing and viability associated with the development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, business development and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters and professional fees for accounting, auditing, tax and consulting services.

We expect that our general and administrative expenses will increase in the future to support continued research and development activities and potential commercialization of our product candidates. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, attorneys and accountants, among other expenses. Additionally, we expect to incur increased expenses associated with being a public company, including costs of additional personnel, accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission, or SEC, requirements, director and officer insurance costs, and investor and public relations costs.

Interest Income (Expense), Net

Interest income (expense), net, primarily consists of interest expense incurred on our credit facility, amortized debt discount related to the fair value of the warrants issued in conjunction with the advances under the credit facility and debt issuance costs, and interest income earned on our cash, cash equivalents and investments.

Other Income (Expense), Net

Other income (expense), net, primarily consists of non-cash changes in the fair value of warrants issued in connection with our credit facility.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally

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accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this prospectus, we believe the following accounting policies used in the preparation of our financial statements require the most significant judgments and estimates.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing purchase orders and open contracts, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by CROs and CMOs in connection with research and development activities for which we have not yet been invoiced.

We contract with CROs and CMOs to conduct clinical and manufacturing and other research and development services on our behalf. We base our expenses related to CROs and CMOs on our estimates of the services received and efforts expended pursuant to quotes and contracts with them. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our CROs or CMOs will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Stock-Based Compensation

We apply the fair value recognition provisions of ASC 718, *Compensation—Stock Compensation*, or ASC 718, for stock-based awards granted to employees and directors for their services on the board of directors. We account for stock-based awards to non-employees in accordance with ASC 505-50, *Equity-Based Payments to Non-Employees*, or ASC 505-50. Determining the amount of stock-based compensation to be recorded

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requires us to develop estimates of the fair value of stock options as of their grant date. We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model. Calculating the fair value of stock-based awards requires that we make subjective assumptions.

Pursuant to ASC 718, we measure stock-based awards granted to employees and members of the board of directors at fair value on the date of grant and recognize the corresponding stock-based compensation expense of those awards on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. We have historically granted stock options with exercise prices equivalent to the fair value of our common stock as of the date of grant.

Pursuant to ASC 505-50, we measure stock-based awards granted to consultants at fair value as the awards vest and recognize the resulting value as expense during the period the related services are rendered, which is typically the vesting period. At the end of each financial reporting period prior to completion of the service, we re-measure the unvested portion of these awards using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The Black-Scholes option-pricing model uses the following inputs: the fair value of our common stock, the expected volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Due to the lack of a public market for our common stock and a lack of company-specific historical and implied volatility data, we have based our computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to us, including stage of product development, life science industry focus, length of trading history and similar vesting provisions. The historical volatility data is calculated based on a period of time commensurate with the expected term assumption. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available or until circumstances change, such that the identified entities are no longer representative companies. In the latter case, more suitable, similar entities whose share prices are publicly available would be utilized in the calculation. We use the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. Under this approach, the weighted-average expected option term is presumed to be the average of the contractual term (ten years) and the vesting term (generally four years) of our stock options. We utilize this method due to lack of historical exercise data and the "plain-vanilla" nature of our stock-based awards. The expected term is applied to the stock option grant group as a whole, as we do not expect substantially different exercise or post-vesting termination behavior among our employee population. For options granted to non-employees, we utilize the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

The fair value of stock options granted to employees and directors was estimated on the date of grant using the Black-Scholes option-pricing model, with the following range of assumptions for the years ended December 31, 2015 and 2016, and the six months ended June 30, 2016 and 2017:

	Years Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
Risk-free interest rate	1.8% - 1.9%	1.3% - 1.7%	1.4% - 1.7%	1.9% - 2.0%
Expected dividend yield	— %	— %	— %	— %
Expected term (in years)	6.25	5.4 - 6.4	5.4 - 6.5	5.6 - 6.3
Expected volatility	85%	77% - 84%	83% - 84%	84% - 87%

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The fair value of stock options granted to consultants was estimated on the date of grant and as the grants are remeasured over the vesting period using the Black-Scholes option-pricing model, with the following range of assumptions for the years ended December 31, 2015 and 2016, and the six months ended June 30, 2016:

	Years Ended December 31,		Six Months Ended June 30,
	2015	2016	2016
Risk-free interest rate	2.4%	1.9% - 2.4%	1.9% - 2.4%
Expected dividend yield	— %	— %	— %
Expected term (in years)	10.0	8.9 - 10.0	8.9 - 10.0
Expected volatility	85%	89% - 96%	89% - 96%

We did not grant any stock options to consultants during the six months ended June 30, 2017. These assumptions represented our best estimates, but the estimates involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

In the first quarter of the year ending December 31, 2017, we made an accounting policy election to recognize forfeitures as they occur upon adoption of guidance per ASU No. 2016-09, *Compensation—Stock Compensation*, or ASU 2016-09. The adoption of ASU 2016-09 did not have a material impact on our consolidated financial statements. In reporting periods prior to the year ending December 31, 2017, we estimated forfeitures at the time of grant and revised the forfeitures rate in subsequent periods as necessary if actual forfeitures differed from estimates.

Through December 31, 2016, the amount of stock-based compensation expense recognized in our consolidated financial statements was based on awards that were ultimately expected to vest. Forfeitures were estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differed from those estimates. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered option.

The following table presents the grant dates, number of underlying shares of common stock and the per share exercise prices of stock options granted between January 1, 2015 and the date of this prospectus, along with the fair value per share utilized to calculate stock-based compensation expense:

Grant Date	Type of Award	Number of Common Shares	Exercise Price of Award per Share(1)	Fair Value of Common Stock per Share on Grant Date	Per Share Estimated Fair Value of Award(2)(3)
March 4, 2015	Option	27,551	$ 1.17	$ 1.17	$ 0.83
June 18, 2015	Option	255,944	$ 1.17	$ 1.17	$ 0.83
March 10, 2016	Option	315,644	$ 1.59	$ 1.59	$ 1.29
June 9, 2016	Option	76,545	$ 1.59	$ 1.59	$ 1.13
September 15, 2016	Option	227,968	$ 1.59	$ 1.59	$ 1.09
February 26, 2017	Option	51,070	$ 4.01	$ 4.01	$ 2.92
August 17, 2017	Option	9,583	$ 4.88	$ 4.88	$ 3.42
September 26, 2017(4)	Option	39,530	$ 5.72	$ 5.72	$ 4.09
September 26, 2017(4)(5)	Option	101,820	$ 5.72	$ 5.72	$ 4.01

(1) The Exercise Price of Award per Share represents the fair value of our common stock on the date of grant, as determined by our board of directors, after taking into account our most recently available contemporaneous valuations of our common stock as well as additional factors that may have changed since the date of such contemporaneous valuations through the date of grant.

(2) The Per Share Estimated Fair Value of Award reflects the fair value of options as estimated at the date of grant using the Black-Scholes option-pricing model.

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(3) For the purposes of recording stock-based compensation for stock options granted to non-employees, we measure the fair value of the award on the service completion date (vesting date). At the end of each reporting period prior to completion of the services, we re-measure the value of any unvested portion of the award based on the then-current fair value of the award and adjust expense accordingly.
(4) The estimated fair value of these options is based upon a valuation analysis as of August 31, 2017 and represents what we believed was the fair value of our common stock on September 26, 2017. As part of our third quarter financial statement close process, we expect to perform a retrospective analysis of the estimated per share fair value of these awards based on the IPO price range established on October 10, 2017.
(5) Represents options granted to members of our Board of Directors, for which vesting is contingent upon a successful IPO within one year of the grant date.

The following table summarizes the classification of our stock-based compensation expense recognized in our statements of operations and comprehensive loss (in thousands):

	Years Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
Research and development	$ 74	$ 68	$28	$ 57
General and administrative	133	183	71	139
Total	$207	$251	$99	$196

As of June 30, 2017, we had $0.9 million of unrecognized compensation expense related to stock option awards, which is expected to be recognized over weighted-average remaining vesting periods of approximately 2.4 years. In future periods, we expect stock-based compensation expense to increase, due in part to our existing unrecognized stock-based compensation expense, potential increases in the value of our common stock and expected additional stock-based awards to continue to attract and retain our employees.

Determination of Fair Value of Common Stock

As a private company with no active public market for our common stock, our board of directors has historically determined the fair value of our common stock on each date of grant, with input from management. Our board of directors periodically determined the estimated per share fair value of our common stock at various dates using contemporaneous valuations performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, or the Practice Aid. Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for us to estimate the fair value of our common stock in connection with our accounting for stock options, as the fair value of our common stock will be its trading price on The Nasdaq Stock Market.

We performed contemporaneous valuations, with the assistance of a third-party specialist, as of November 6, 2014, February 15, 2016, December 31, 2016, April 30, 2017 and August 31, 2017, which resulted in valuations of our common stock of $1.17, $1.59, $4.01, $4.88 and $5.72 per share, respectively. In conducting the valuations, we considered all objective and subjective factors that we believed to be relevant for each valuation conducted, including our best estimate of our business condition, prospects and operating performance at each valuation date. Within the valuations performed, a range of factors, assumptions and methodologies were used. The significant factors included:

- the lack of an active public market for our common stock and convertible preferred stock;
- the prices at which we sold shares of our convertible preferred stock in arm's length transactions and the superior rights, preferences and privileges of the convertible preferred stock relative to our common stock, including the liquidation preferences of our preferred stock;

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- our results of operations and financial condition, including cash on hand and borrowings under our credit facility;
- the material risks related to our business;
- our stage of development and business strategy;
- the composition of, and changes to, our management team and board of directors;
- the market performance of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed initial public offerings, or IPOs, of companies in the life sciences and biotechnology sectors; and
- the likelihood of achieving a liquidity event such as an IPO given prevailing market conditions.

Historically, the dates of our contemporaneous valuations have not coincided with the dates of our stock-based compensation grants. In determining the exercise prices of the stock options granted, our board of directors considered, among other things, the most recent contemporaneous valuations of our common stock and our assessment of additional objective and subjective factors we believed were relevant as of the grant date. The additional factors considered when determining any changes in fair value of our common stock between the most recent contemporaneous valuation and the grant dates included the status of our stage of research and development, our operating and financial performance and current business conditions.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates are management's best estimates and include assumptions regarding our future operating performance, the time to completing an IPO or other liquidity event, the related company valuations associated with such events and the determinations of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per common share could have been different.

Common Stock Valuation Methodologies

Our contemporaneous common stock valuations were prepared in accordance with the guidelines in the Practice Aid, which prescribes several valuation approaches for determining the value of an enterprise, such as the cost, market and income approaches, and various methodologies for allocating the value of an enterprise to its capital structure and specifically the common stock.

Our common stock valuation of November 6, 2014 was prepared using the backsolve method to calculate the total equity value and the option-pricing method, or OPM, to allocate the total equity value. The backsolve method derives the implied equity value for one type of equity security from a contemporaneous transaction involving another type of security. Our common stock valuation as of February 15, 2016 was prepared using the backsolve method to calculate the total equity value and a hybrid of the OPM and probability-weighted expected return method, or PWERM, including a future IPO scenario, to allocate the total equity value. We used the backsolve method to calculate the total equity value of our company in the November 6, 2014 and February 15, 2016 valuations as we had recently completed convertible preferred stock financings that represented recent transactions in our securities that should be considered in estimating the fair value of our equity per the Practice Aid. Our common stock valuations of December 31, 2016 and April 30, 2017 were prepared using the guideline public company method, or GPC, which includes comparisons to publicly traded companies in our industry that recently completed IPOs, to calculate the total equity value and a hybrid of the OPM and PWERM, including a future IPO scenario, to allocate the total equity value. The GPC was used in these valuations as there were no recent equity financings or other transactions involving the Company's equity securities, yet there were several recently completed IPOs of comparable companies in the industry.

Option-Pricing Method (OPM). The OPM treats each class of common stock and convertible preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at

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which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the convertible preferred stock liquidation preferences at the time of a liquidity event, such as a strategic sale, merger or IPO. The common stock is modeled as a call option on the underlying equity value at a predetermined exercise price. In the model, the exercise price is based on a comparison with the total equity value rather than, as in the case of a regular call option, a comparison with a per share stock price. Thus, common stock is considered to be a call option with a claim on the enterprise at an exercise price equal to the remaining value immediately after the convertible preferred stock liquidation preference is paid.

The OPM uses the Black-Scholes option-pricing model to price the call options. This model defines the securities' fair values as functions of the current fair value of a company and uses assumptions, such as the anticipated timing of a potential liquidity event and the estimated volatility of the equity securities. The aggregate value of the common stock derived from the OPM is then divided by the number of shares of common stock outstanding to arrive at the per share value.

We used the OPM backsolve approach to estimate enterprise value under the OPM. The OPM backsolve approach uses the OPM to calculate the implied equity value based on recent sales of the company's securities. For the OPM, we based our assumed volatility factor on the historical trading volatility of our publicly traded peer companies. At each valuation date, we determined the appropriate volatility to be used, considering such factors as our expected time to a liquidity event and our stage of development.

To derive the fair value of our common stock using the OPM, we calculated the proceeds to the common stockholders based on the preferences and priorities of the convertible preferred and common stock. We then applied a discount for lack of marketability to the common stock to account for the lack of access to an active public market.

Probability-Weighted Expected Return Method (PWERM). The PWERM is a scenario-based methodology that estimates the fair value of common stock-based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. A discount for lack of marketability is then applied to the common stock to account for the lack of access to an active public market.

Hybrid Method. The hybrid method is a PWERM where the equity value in one of the scenarios is calculated using an OPM. In the hybrid method used by us, we considered two types of future-event scenarios: an IPO and an unspecified liquidity event. The equity value for the IPO scenario was determined using the GPC method under the market approach. The equity value for the unspecified liquidity event scenario was determined using a backsolve method. The relative probability of each type of future-event scenario was determined based on an analysis of market conditions at the time, including then-current IPO valuations of similarly situated companies, and our expectations as to the timing and likely prospects of the future-event scenarios. A discount for lack of marketability is then applied to the common stock to account for the lack of access to an active public market.

To derive the fair value of the common stock for each scenario using the hybrid method, we calculated the proceeds to the common stockholders based on the preferences and priorities of the convertible preferred and common stock. We then applied a discount for lack of marketability to the common stock to account for the lack of access to an active public market.

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Warrant Valuation

We issued warrants to purchase shares of our Series A and Series C convertible preferred stock in conjunction with the advances made under our credit facility. These warrants are classified as liabilities as they either conditionally or unconditionally obligate us to transfer assets regardless of the timing of the redemption feature or price of the underlying convertible preferred stock. The warrants were initially recorded at their grant date fair value and are subject to revaluation at each balance sheet date. Changes in the fair value of the warrants are recorded as a component of other income (expense) in the statements of operations and comprehensive loss, until the earlier of their exercise or expiration or the completion of a liquidation event, at which time the warrant liability may be reclassified to stockholders' (deficit) equity if the criteria for recording the warrant as an equity instrument are met.

The fair value of the warrants is estimated using the Black-Sholes model, which incorporates assumptions and estimates to value these warrants. We assess these assumptions and estimates on a periodic basis based on information available to us on each valuation date. Such assumptions and estimates include: the fair value of the Series A and Series C convertible preferred stock, the remaining contractual term of the warrants, the risk-free interest rate applicable to the remaining contractual term, the expected dividend yield and the expected volatility of the price of the underlying common stock into which the preferred stock is convertible. We estimate the fair value of our Series A and Series C convertible preferred stock upon the issuance of the warrants and at each reporting period based upon our common stock valuations which include a derived fair value for such shares of preferred stock. We have historically been a private company and lack company-specific historical and implied volatility information of our stock. Therefore, we estimate expected stock volatility based on the historical volatility of publicly traded comparable companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods that approximately equal the remaining contractual term of the warrants. We assumed no dividend yield based on the fact that we have never paid or declared dividends, and do not expect to pay or declare dividends in the future.

In connection with this offering, all outstanding shares of our preferred stock will be converted to common stock. The convertible preferred warrants will therefore become exercisable into common stock instead of convertible preferred stock and the fair value of the warrant liability may be reclassified to stockholders' (deficit) equity if the criteria for recording the warrants as an equity instrument are met.

Results of Operations

Comparison of the Six Months Ended June 30, 2016 and 2017

The following table summarizes our results of operations for the six months ended June 30, 2016 and 2017 (in thousands):

	Six Months Ended June 30,		Dollar Change
	2016	2017	
Operating expenses:			
Research and development	$10,025	$ 7,809	$(2,216)
General and administrative	2,057	2,208	151
Total operating expenses	12,082	10,017	(2,065)
Other income (expense):			
Interest income (expense), net	(71)	(255)	184
Other income (expense), net	1	(31)	32
Other income (expense), net	(70)	(286)	216
Net loss	$12,152	$10,303	$(1,849)

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Research and Development Expenses

Research and development expense decreased by $2.2 million from $10.0 million for the six months ended June 30, 2016 to $7.8 million for the six months ended June 30, 2017. The following table summarizes our research and development expenses for the six months ended June 30, 2016 and 2017 (in thousands):

	Six Months Ended June 30,		Dollar Change
	2016	2017	
Clinical development external costs	$ 2,972	$2,482	$ (490)
Manufacturing external costs	4,706	1,829	(2,877)
Employee compensation and benefits	1,194	2,081	887
Other	1,153	1,417	264
Total research and development expenses	$10,025	$7,809	$(2,216)

The decrease in research and development expense was primarily attributable to the following:

- Our manufacturing external costs decreased by $2.9 million from $4.7 million for the six months ended June 30, 2016 to $1.8 million for the six months ended June 30, 2017.
  - We entered into a contract manufacturing agreement with a new CMO for the manufacturing of our ALLN-177 drug substance in June 2015. We incurred significant costs setting up the new CMO in the second half of 2015 and the duration of 2016. Costs incurred at this CMO were $1.0 million and $0.2 million during the six months ended June 30, 2016 and 2017, respectively;
  - During the six months ended June 30, 2016, we purchased consumables and raw materials to supply our planned pre-engineering, engineering and clinical batches. These consumables and raw materials were expensed at the time of purchase. Our costs for consumables and raw materials were $1.6 million and $0.3 million for the six months ended June 30, 2016 and 2017, respectively; and
  - During the six months ended June 30, 2016, we conducted considerable process development and manufactured several pre-engineering and engineering batches of product for ALLN-177 as we scaled our manufacturing process and manufactured material for our clinical trials. Costs associated with these activities were $1.0 million for the six months ended June 30, 2016. During the six months ended June 30, 2017, we conducted less process development and batch production consisted only of engineering batches. Costs associated with these activities were $0.4 million for the six months ended June 30, 2017.
- Our clinical development external costs for the six months ended June 30, 2016 included $1.3 million of costs for our Phase 2 clinical trial for ALLN-177 (Study 649). This trial stopped enrolling subjects in June 2016. Partially offsetting this decrease in clinical development costs from the prior year period were increased costs for our Phase 2 clinical trial for ALLN-177 (Study 713) during the six months ended June 30, 2017. Our costs for Study 713 were $0.9 million and $1.4 million for the six months ended June 30, 2016 and 2017, respectively, as we completed enrollment for Study 713 in early 2017 and incurred expenses related to the completion of this trial, finalization of the database, and analysis of the data. In addition, we incurred costs of $0.3 million during the six months ended June 30, 2017 as we conducted and completed a prospective controlled clinical trial (Study 204) in subjects with secondary hyperoxaluria. We initiated this study during the fourth quarter of the year ending December 31, 2016 and therefore did not incur any costs relating to the Study 204 during the six months ended June 30, 2016; and
- Our employee compensation and benefits costs increased by $0.9 million for the six months ended June 30, 2017. The increase is primarily due to an overall increase in research and development headcount. We had 13 employees in research and development at June 30, 2016 compared to 20 employees in research and development at June 30, 2017.

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We expect that our research and development expenses will increase in future periods as we continue our clinical development of ALLN-177, scale our manufacturing processes for ALLN-177 and advance development of ALLN-346.

General and Administrative Expenses

General and administrative expense increased by $151,000 from $2.1 million for the six months ended June 30, 2016 to $2.2 million for the six months ended June 30, 2017. The following table summarizes our general and administrative expenses for the six months ended June 30, 2016 and 2017 (in thousands):

	Six Months Ended June 30,		Dollar Change
	2016	2017	
Employee compensation and benefits	$ 823	$1,209	$ 386
Consulting and professional services	469	442	(27)
Market research and commercialization planning	445	271	(174)
Other	320	286	(34)
Total general and administrative expenses	$2,057	$2,208	$ 151

The increase in general and administrative expense was primarily attributable to the following:

- Our employee compensation and benefits costs increased by $0.4 million. The increase is primarily due to the addition of three new employees in the second quarter of the year ended December 31, 2016, including our Chief Financial Officer, who were employed for the full six months ended June 30, 2017. Our stock-based compensation also increased $68,000 from $71,000 for the six months ended June 30, 2016 to $139,000 for the six months ended June 30, 2017; and
- Our market research and commercialization planning costs decreased by $174,000, partially offsetting the increase in our employee-compensation and benefits-related costs during the six months ended June 30, 2017. During the six months ended June 30, 2016, we engaged an independent third party to conduct a study to assess the market opportunity for ALLN-177.

We expect that our general and administrative expense will increase in future periods as we expand our operations and incur additional costs in connection with being a public company.

Interest Income (Expense), net

Interest income (expense), net consists of interest income earned on our cash, cash equivalents and short-term investments, interest expense charged on our outstanding debt, and amortization of our debt discount related to the fair value of the warrants. It increased $0.2 million from $(0.1) million for the six months ended June 30, 2016 to $(0.3) million for the six months ended June 30, 2017. The increase was attributable to additional interest costs associated with the refinancing of our credit facility in May 2016.

Other Income (Expense), net

Other income (expense), net consists primarily of non-cash changes in the fair value of warrants issued in connection with our credit facility.

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Comparison of the Years Ended December 31, 2015 and 2016

The following table summarizes our results of operations for the years ended December 31, 2015 and 2016 (in thousands):

	Years Ended December 31,		Dollar Change
	2015	2016	
Operating expenses:			
Research and development	$ 11,540	$ 20,103	$ 8,563
General and administrative	2,365	4,083	1,718
Total operating expenses	13,905	24,186	10,281
Other income (expense):			
Interest income (expense), net	(335)	(200)	135
Other income (expense), net	(7)	(121)	(114)
Other income (expense), net	(342)	(321)	21
Net loss	$(14,247)	$(24,507)	$(10,260)

Research and Development Expense

Research and development expense increased by $8.6 million from $11.5 million for the year ended December 31, 2015 to $20.1 million for the year ended December 31, 2016. The following table summarizes our research and development expenses for the years ended December 31, 2015 and 2016 (in thousands):

	Years Ended December 31,		Dollar Change
	2015	2016	
Clinical development external costs	$ 3,517	$ 7,275	$3,758
Manufacturing external costs	4,480	7,068	2,588
Employee compensation and benefits	2,018	3,074	1,056
Other	1,525	2,686	1,161
Total research and development expenses	$11,540	$20,103	$8,563

The increase in research and development expense was primarily attributable to the following:

- Our clinical development external costs increased by $3.8 million from $3.5 million for the year ended December 31, 2015 to $7.3 million for the year ended December 31, 2016:
  - Study 649 expense increased by $0.8 million from $1.4 million for the year ended December 31, 2015 to $2.2 million for the year ended December 31, 2016. Expenses during the year ended December 31, 2015 consisted primarily of startup and related costs and initial subject-related costs, as we enrolled our first subject in the trial in September 2015. Expenses in the year ended December 31, 2016 included a majority of the trial's CRO and subject costs as well as close-out costs;
  - Study 713 expense increased by $2.2 million from $0.8 million for the year ended December 31, 2015 to $3.0 million for the year ended December 31, 2016. Expenses during the year ended December 31, 2015 consisted primarily of startup and related costs. We enrolled our first subject into the trial in December 2015. The trial continued for the duration of the year ended December 31, 2016 and the vast majority of subjects were enrolled during the year ended December 31, 2016, which increased our CRO and subject enrollment costs; and
  - We initiated and conducted Study 204 in the year ended December 31, 2016. Expenses for this trial were $0.5 million for the year ended December 31, 2016. There were no expenses related to this trial during the year ended December 31, 2015.

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- Our manufacturing external costs increased by $2.6 million from $4.5 million for the year ended December 31, 2015 to $7.1 million for the year ended December 31, 2016:
  - During the year ended December 31, 2016, we conducted considerable process development and manufactured several pre-engineering, engineering, and clinical trial batches of product for ALLN-177 as we scaled our manufacturing process and manufactured material for our clinical trials. Costs associated with these activities were $1.7 million in the year ended December 31, 2016. During the year ended December 31, 2015, we incurred process development costs of $0.9 million;
  - During the year ended December 31, 2016 we purchased consumables and raw materials to supply our planned pre-engineering, engineering and clinical trial batches. These consumables and raw materials were expensed at the time of purchase. Our costs for consumables and raw materials were $0.3 million and $1.7 million for the years ended December 31, 2015 and 2016, respectively; and
  - Consulting costs increased by $0.4 million from $0.2 million for the year ended December 31, 2015 to $0.6 million for the year ended December 31, 2016 to support our increased drug substance and drug product activities.
- Our employee compensation and benefits costs increased by $1.1 million from $2.0 million for the year ended December 31, 2015 to $3.1 million for the year ended December 31, 2016. The increase is primarily due to an overall increase in research and development headcount. We had nine employees in research and development at December 31, 2015 compared to 18 employees in research and development at December 31, 2016; and
- Other costs increased by $1.2 million from $1.5 million for the year ended December 31, 2015 to $2.7 million for the year ended December 31, 2016. We had $0.3 million of external costs for our ALLN-346 product candidate for the year ended December 31, 2016, with no comparable costs for the year ended December 31, 2015. Our project management costs also increased by $0.5 million from $0.1 million for the year ended December 31, 2015 to $0.6 million for the year ended December 31, 2016. We engaged a third party consulting firm during the fourth quarter of the year ended December 31, 2015 to provide project management consulting services, which were provided to us for the duration of the year ended December 31, 2016.

General and Administrative Expenses

General and administrative expense increased by $1.7 million from $2.4 million for year ended December 31, 2015 to $4.1 million for the year ended December 31, 2016. The following table summarizes our general and administrative expenses for the years ended December 31, 2015 and 2016 (in thousands):

	Years Ended December 31,		Dollar Change
	2015	2016	
Employee compensation and benefits	$1,319	$1,939	$ 620
Consulting and professional services	500	843	343
Market research and commercialization planning	265	674	409
Other	281	627	346
Total general and administrative expenses	$2,365	$4,083	$1,718

The increase in general and administrative expense was primarily attributable to the following:

- Our employee compensation and benefits costs increased by $0.6 million. The increase was primarily related to an increase in the number of employees, including the addition of our Chief Financial Officer, who joined us in June 2016. We had four general and administrative employees at December 31, 2015 compared to seven employees at December 31, 2016; and

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- Our market research and commercialization planning costs increased by $0.4 million. During the year ended December 31, 2016, we engaged an independent third party to conduct a study to assess the market opportunity for ALLN-177. We incurred $330,000 of costs for the year ended December 31, 2016 for this study.

Interest Income (Expense), net

Interest income (expense), net decreased by $0.1 million from $(0.3) million for the year ended December 31, 2015 to $(0.2) million for the year ended December 31, 2016. The decrease was attributable to interest income earned on our investment portfolio attributable to investments we made after our Series C convertible preferred stock financing in November 2015, partially offset by additional interest costs associated with the refinancing of our credit facility in May 2016 and an increase in amounts outstanding under the loan in the year ended December 31, 2016 as compared to the year ended December 31, 2015.

Other Income (Expense), net

Other income (expense), net consists primarily of non-cash changes in the fair value of the warrants issued in connection with our credit facility.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations from inception through June 30, 2017 through gross proceeds of $96.0 million from sales of our convertible preferred stock and borrowings of $10.0 million under our credit facility with SVB. The following table provides information regarding our total cash, cash equivalents and short term investments at December 31, 2015 and 2016 and June 30, 2017 (in thousands):

	December 31,		June 30,
	2015	2016	2017
Cash and cash equivalents	$69,011	$25,250	$34,713
Short term investments	—	23,505	3,249
Total cash, cash equivalents and short term investments	$69,011	$48,755	$37,962

On August 18, 2014, we entered into a loan and security agreement with SVB, or the credit facility, which was subsequently amended on December 22, 2014 and May 2, 2016. The credit facility initially provided up to $7.0 million principal in term loans, $3.8 million of which was funded at the time we entered into the original agreement and $3.2 million of which was funded in March 2015. As amended in May 2016, the loan and security agreement provides for up to $10.0 million in term loans, $7.5 million of which was funded when we entered into the second amendment to the loan and security agreement, of which we received $1.6 million in net proceeds after deducting $5.3 million for repayment of the original advances and $0.6 million for interest and debt issuance costs. The remaining $2.5 million was funded in December 2016 upon our achievement of certain milestones. The May 2016 and December 2016 advances have a floating annual interest rate equal to the greater of 4.0% or 0.5% above the prime rate.

The repayment schedule provides for interest only payments for eighteen months, beginning in May 2016. Following the interest only period, the loan repayment schedule provides for 30 equal monthly payments of principal plus interest. The loan and security agreement also provides for a final interest payment equal to 8.25% of the total which is due on the earliest of the loan maturity date, acceleration of the loan in the case of an event of default, at the time of prepayment of the facility or termination of the agreement. We have the option to prepay the outstanding balance of the term loan in full, subject to a prepayment fee of 0%—2% depending upon when the prepayment occurs. The term loan facility matures on May 1, 2020.

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The borrowings under the loan and security agreement are secured by a lien on all of our assets except intellectual property. The loan and security agreement contains customary representations, warranties and covenants by us, including negative covenants restricting our activities, such as disposing of our business or certain assets, changing our business, management, ownership or business locations, incurring additional debt or liens or making payments on other debt, making certain investments and declaring dividends, acquiring or merging with another entity, engaging in transactions with affiliates or encumbering intellectual property. The obligations under the loan and security agreement are subject to acceleration upon occurrence of specified events of default, including a material adverse change in our business, operations or financial or other condition.

In connection with entering into the loan and security agreement, in August 2014, we granted to SVB a warrant to purchase 142,856 shares of our Series A preferred stock at an exercise price of $0.98 per share. In connection with entering into the second amendment to the loan and security agreement, in May 2016, we granted to SVB a warrant to purchase 37,736 shares of our Series C preferred stock at an exercise price of $2.65 per share. Each warrant may be exercised at the option of SVB either by delivery of the exercise price in cash or by a cashless exercise, and will expire in August 2024 and May 2026, respectively. Following the consummation of this offering, these warrants will be exercisable for shares of our common stock.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2015 and 2016 and for the six months ended June 30, 2016 and 2017 (in thousands):

	Years Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
Net cash used in operations	$(13,175)	$(23,394)	$(10,391)	$(10,708)
Net cash provided by (used in) investing activities	5	(23,762)	(33,684)	20,169
Net cash provided by financing activities	55,295	3,395	895	2
Net increase (decrease) in cash and cash equivalents	$ 42,125	$(43,761)	$(43,180)	$ 9,463

Net Cash Used in Operating Activities

The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital.

Net cash used in operating activities was $10.7 million for the six months ended June 30, 2017 compared to $10.4 million for the six months ended June 30, 2016. The increase in cash used in operating activities of $0.3 million was attributable to a $2.4 million decrease in working capital, including a decrease of $2.3 million in accounts payable and accrued expenses, partially offset by a reduction in net loss of $1.9 million and an increase in non-cash expenses of $0.2 million.

Net cash used in operating activities was $23.4 million for the year ended December 31, 2016 compared to $13.2 million for the year ended December 31, 2015. The increase in cash used in operating activities of $10.2 million was attributable to:

- an increase in net loss of $10.3 million;
- an increase in non-cash items of $0.3 million resulting primarily from increases in amortization of premium on investments and the change in the fair value of the warrant liability; and
- an increase of $0.2 million in changes in the components of working capital.

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Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $20.2 million for the six months ended June 30, 2017 compared to net cash used in investing activities of $33.7 million for the six months ended June 30, 2016. The increase in cash flows from investing activities of $53.9 million was attributable to a decrease in purchases of short term investments of $37.9 million and an increase in maturities of short-term investments of $16.0 million, as we converted short-term investments to cash and cash equivalents to fund our operations.

Net cash used in investing activities was $23.8 million for the year ended December 31, 2016 compared to net cash provided by investing activities of $5,000 for the year ended December 31, 2015. The increase in cash used for investing activities of $23.8 million was attributable to:

- an increase in purchases of short-term investments of $53.2 million partially offset by maturities of $29.6 million; and
- an increase in purchases of property and equipment of $0.1 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $2,000 for the six months ended June 30, 2017 compared to $0.9 million for the six months ended June 30, 2016. The decrease in cash provided by financing activities of $0.9 million was attributable to our net proceeds during the six months ended June 30, 2016 from the refinancing of our loan payable. We received $7.5 million of advances under our amended credit facility and we repaid the $6.3 million outstanding balance and certain interest and debt issuance costs under the original credit facility. There were no advances received or principal payments made on our credit facility during the six months ended June 30, 2017.

Net cash provided by financing activities was $3.4 million for the year ended December 31, 2016 compared to $55.3 million for the year ended December 31, 2015. The decrease in cash provided by financing activities of $51.9 million was attributable to:

- the sale of Series C convertible preferred stock in November 2015 partially offset by;
- a $0.9 million increase in net proceeds from the refinancing of our credit facility.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development for, initiate later stage clinical trials for, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect that the net proceeds from this offering, together with our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into 2020. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the costs of conducting future clinical trials of ALLN-177;
- the costs of manufacturing additional material for our planned pivotal Phase 3 clinical program, planned Phase 2 basket clinical trial and potential future clinical studies we might conduct for ALLN-177;

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- the costs of scaling up our manufacturing process for ALLN-177 to prepare for the filing of a potential BLA and commercialization if our clinical development program is successful;
- the advancement of ALLN-346;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing and clinical trials for other potential product candidates we may develop, if any;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and our research and development activities; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. With the exception of our credit facility, we do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your rights as a common stockholder. Additional debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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Contractual Obligations

The following table summarizes our significant contractual obligations as of payment due date by period at June 30, 2017 (in thousands):

	Total	Less than 1 Year	1 to 3 years	3 to 5 Years	More than 5 years
Credit facility(1)	$11,450	$ 2,479	$ 8,971	$ —	$ —
Operating lease obligations(2)	464	369	95	—	—
Total	$11,914	$ 2,848	$ 9,066	$ —	$ —

(1) Consists of repayment obligations under our credit facility with SVB, including interest.
(2) Represents future minimum lease payments under our non-cancelable operating leases which expire through February 2019. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.

Under a license agreement with Althea Technologies, Inc. (now known as Ajinomoto Althea, Inc.), or Althea, which we entered into in March 2012, as amended in March 2016, we reimbursed Althea for patent-related fees of $0.1 million and issued 88,186 shares of common stock to Althea. In addition, we are obligated to pay milestone payments and royalties of a mid-single digit percentage of net sales. Milestone payments are triggered upon the achievement of specified regulatory milestones that could total up to $31.0 million and sales-based milestones that could total up to $25.0 million. The milestone payments are not creditable against royalties. Actual amounts due under the agreement will vary depending on the number of products developed, the type and development path of the products, and other related factors. As of June 30, 2017, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. We have the right to terminate the agreement for convenience upon 60 days prior written notice to Althea. As a result, no amounts are included in the table above. See “Business—Althea License Agreement” for a more detailed description of this agreement.

We enter into agreements in the normal course of business with CROs for clinical trials, CMOs for clinical supply manufacturing, professional consultants for expert advice and other vendors for other services for operating purposes. We have not included these payments in the table of contractual obligations above since the contracts do not contain any minimum purchase commitments and are cancelable at any time by us, generally upon 30 days prior written notice and therefore we believe that our non-cancelable obligations under these agreements are not material.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk related to changes in interest rates. As of June 30, 2017, our cash equivalents consisted of primarily of short-term money market funds. As of June 30, 2017, our short-term investments consisted of United States Treasury securities and corporate notes with maturities of less than one year. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term nature of the investments in our portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio or on our financial position or results of operations.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with foreign vendors that are located in Europe. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

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Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2015 and 2016 or the six months ended June 30, 2016 and 2017.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, or EGC, we intend to rely on certain of these exemptions, including exemptions from the requirement to provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an EGC until the earlier of: the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering; the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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BUSINESS

Overview

We are a late-stage clinical biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders. We are focused on metabolic disorders that result in excess accumulation of certain metabolites, such as oxalate and urate, that can cause kidney stones, damage the kidney, and potentially lead to chronic kidney disease, or CKD, and end-stage renal disease. Our proprietary technological approach enables us to design and develop stable, non-absorbable oral enzyme therapies that remain in the gastrointestinal, or GI, tract, where the enzyme can degrade these metabolites, allowing for removal from the body through the bowel. This mechanism of action reduces the accumulation of the metabolites in the body and therefore limits the burden on the kidney to filter and then excrete the metabolite in the urine. The data from our clinical trials and numerous academic studies suggest the potential for GI elimination of these metabolites to reduce the chronic disease burden on the kidney and other organ systems. Our lead product candidate, ALLN-177, is a first-in-class, oral enzyme therapeutic that we are developing for the treatment of hyperoxaluria, a metabolic disorder characterized by markedly elevated urinary oxalate levels and commonly associated with kidney stones, CKD and other serious kidney diseases. There are currently no approved therapies for the treatment of hyperoxaluria.

ALLN-177, a crystalline formulation of the enzyme oxalate decarboxylase, has been designed to specifically degrade oxalate within the GI tract, limiting systemic absorption of the metabolite into the bloodstream. Oxalate is endogenously produced as an end product of normal cellular metabolism and is also absorbed through the GI tract from a typical diet. Humans lack the innate capacity to digest oxalate and primarily depend on renal excretion to eliminate it from the body. Although oxalate has no identified biological function, it is known to damage the kidney when present in excess amounts, a condition called hyperoxaluria. Hyperoxaluria is characterized by significantly elevated oxalate levels in the urine, or urinary oxalate excretion, due to either overproduction of oxalate by the liver from a genetic defect, called primary hyperoxaluria, or from over absorption of oxalate from the diet, called secondary hyperoxaluria. Secondary hyperoxaluria is further characterized either as enteric, resulting from a chronic and unremediable underlying GI disorder associated with malabsorption, such as bariatric surgery complications or Crohn's disease, which predisposes patients to excess oxalate absorption, or idiopathic, meaning the underlying cause is unknown. Enteric hyperoxaluria is the more severe type of secondary hyperoxaluria.

We have conducted a robust clinical development program of ALLN-177, including three Phase 2 clinical trials, which demonstrated reductions of urinary oxalate excretion in patients with secondary hyperoxaluria, particularly in patients with enteric hyperoxaluria. ALLN-177 has also been well tolerated in clinical trials to date. Based on these data, the high unmet medical need, the enzyme's specific mechanism of action, and the significant market opportunity, we are initially developing ALLN-177 for adult patients with enteric hyperoxaluria. We are in discussions with the U.S. Food and Drug Administration, or the FDA, to finalize the design of our planned pivotal Phase 3 program in enteric hyperoxaluria and we expect to initiate the first of two Phase 3 clinical trials in the first quarter of 2018, with topline data anticipated in the second half of 2019. The FDA has also granted separate orphan drug designations for ALLN-177 for the treatment of primary hyperoxaluria and for the treatment of pediatric hyperoxaluria. In addition, the European Commission has granted orphan designation for ALLN-177 for the treatment of primary hyperoxaluria. In light of these designations, we are planning to initiate a Phase 2 clinical trial in the first quarter of 2018 in adolescents and adults with primary hyperoxaluria or severe forms of secondary hyperoxaluria, both of which can lead to systemic oxalosis, a potentially fatal disorder associated with excess levels of oxalate in the blood, or hyperoxalemia, with interim data expected in the second half of 2018 and topline data anticipated in 2019.

The first clinical manifestation of hyperoxaluria is often a kidney stone; however, the disorder can be variable in its presentation. Patients with severe hyperoxaluria may have recurrent kidney stones or experience infrequent or no kidney stones, yet still develop CKD and end-stage renal disease, which can be fatal. Systemic

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oxalosis, which typically occurs in patients with primary or severe secondary hyperoxaluria and declining kidney function, refers to the presence of excess oxalate throughout the body, including the blood, bones, joints, eyes and heart.

We estimate there are approximately 200,000 to 250,000 patients in the United States with enteric hyperoxaluria and kidney stones. We plan to target this market initially. We believe that a therapeutic agent that reduces urine oxalate levels in this population could be commercialized into a potential multi-billion dollar U.S. market without any approved therapies at present. Primary hyperoxaluria, an ultra-rare genetic disease, is estimated to affect approximately 1 in 58,000, or approximately 5,000 patients, in the United States. Among patients with primary hyperoxaluria, about 50 percent will have kidney failure by age 15, and about 80 percent will have kidney failure by age 30. There are no FDA approved therapies for primary hyperoxaluria, and the most severe patients may be treated with a liver and/or kidney transplant. Patients with enteric hyperoxaluria can have levels of urinary oxalate excretion as high as patients with primary hyperoxaluria and a comparable renal burden.

We believe our proprietary know-how in enzyme technology allows us to design, formulate and deliver non-absorbed and stable enzymes orally and in sufficient doses for activity in the GI tract. This approach enables us to develop enzyme therapies that degrade metabolites within the GI tract, thereby preventing their absorption, which reduces potentially toxic metabolite levels in the blood and urine, and in turn, diminishes the disease burden on the kidney over time. The general therapeutic approach of deploying a non-absorbed drug into the GI tract to reduce metabolic disease burden in patients with kidney disease has been proven successful in several therapeutic categories. Utilizing our proprietary technological approach, we conceived and developed ALLN-177, an oral biologic product candidate. Manufacturing biologic drugs is generally a complex and cost intensive process because they are manufactured in living systems or cells and tend to be large complex molecules. Since the living systems used to produce biologics can be sensitive to very minor changes in manufacturing techniques, small process differences can significantly affect the nature of the finished biologic and, most importantly, the way it functions in the body. Our proprietary and scalable manufacturing capabilities enable us to produce large quantities of our oral enzyme product candidates sufficiently to support our clinical and commercial strategy, with costs anticipated to be comparable to small molecule therapeutics. We have issued patents covering ALLN-177 in addition to the trade secrets that cover our manufacturing process.

We have assembled a seasoned management team with extensive experience in drug discovery, development, manufacturing and commercialization. We are supported by a top-tier investor syndicate including Frazier Healthcare Partners, Third Rock Ventures, Bessemer Venture Partners, HBM Healthcare Investments, Pharmstandard International S.A., Partner Fund Management, Fidelity Management & Research Company and other investors and have raised approximately $96.0 million in equity financing to date.

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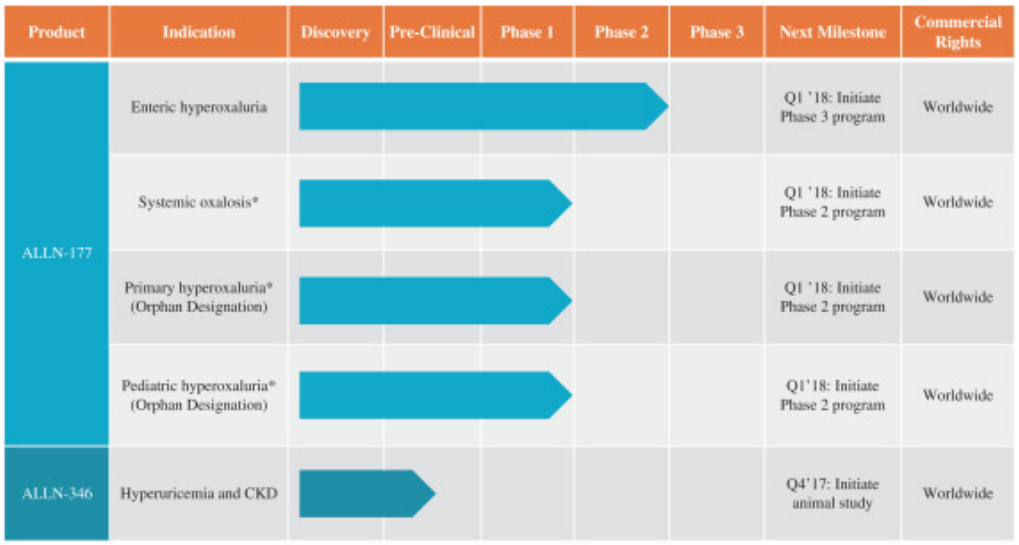
Our Product Candidate Pipeline

Using our proprietary technological approach, we have developed a pipeline of first-in-class, oral, non-absorbed enzyme therapeutic candidates to treat patients with rare and severe metabolic disorders that affect the kidney. Our lead product candidate, ALLN-177, is an oral enzyme therapeutic that we are developing for the treatment of hyperoxaluria, for which there are currently no approved therapies. Our second product candidate, ALLN-346, is being developed for patients with hyperuricemia and moderate to severe CKD. Hyperuricemia, or elevated levels of uric acid in the blood, is commonly associated with gout as well as kidney stones and kidney disorders.



Strategy

Our goal is to become the leader in developing and commercializing first-in-class, oral, non-absorbed enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders. To achieve this goal, we are executing on the following strategy:

- ***Obtain regulatory approval in the United States for our lead product candidate, ALLN-177, for enteric hyperoxaluria in adults***—We have conducted a robust Phase 2 clinical development program of ALLN-177 in patients with secondary hyperoxaluria, which demonstrated significant reductions of urinary oxalate excretion in patients with enteric hyperoxaluria. Based on these data and the high unmet need, we are initially developing ALLN-177 for enteric hyperoxaluria. Moreover, we believe the mechanism of action of ALLN-177, which degrades oxalate in the GI tract, is particularly well-targeted to treat enteric hyperoxaluria where excess oxalate absorption is driven by an underlying GI disorder. We are currently in discussions with the FDA to finalize the design of our planned pivotal Phase 3 program and we currently expect to initiate the first of two Phase 3 clinical trials for ALLN-177 in the first quarter of 2018, with topline data anticipated in the second half of 2019.
- ***Commercialize ALLN-177***—We have worldwide commercialization and development rights to ALLN-177. We intend to independently pursue regulatory approval of ALLN-177 in patients with enteric hyperoxaluria in the United States and, if approved, to commercialize the product by building a focused commercial organization in the United States specifically to target nephrologists and urologists who treat patients with hyperoxaluria, particularly at kidney stone clinics.

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- ***Advance development of ALLN-177 for other severe forms of hyperoxaluria***—The FDA has granted separate orphan drug designations for ALLN-177 for the treatment of primary hyperoxaluria and for the treatment pediatric hyperoxaluria (primary and secondary). In light of these designations, we are planning to initiate a Phase 2 clinical trial in the first quarter of 2018 in adolescents and adults with primary hyperoxaluria or severe forms of secondary hyperoxaluria, both of which can lead to systemic oxalosis, with interim data expected in the second half of 2018 and topline data anticipated in 2019. In addition, we plan to seek breakthrough designation where appropriate.
- ***Seek regulatory approval in Europe for our lead product candidate, ALLN-177***—We plan to pursue regulatory approval for patients with severe hyperoxaluria in Europe in conjunction with our pursuit of approval in the United States. We plan to obtain National Scientific Advice from select countries in Europe by the end of 2017 and to discuss the results of our Phase 2 clinical program in secondary hyperoxaluria and our proposed pivotal Phase 3 program in enteric hyperoxaluria. In addition, the European Commission has granted orphan designation for ALLN-177 for the treatment of primary hyperoxaluria.
- ***Advance development of ALLN-346***—Utilizing our expertise in enzyme therapeutics and proprietary technological approach, we have designed ALLN-346 to degrade urate in the GI tract. We intend to pursue the development of ALLN-346 for patients with hyperuricemia and CKD. These patients are challenging to manage due to limitations of existing therapies, such as poor tolerability, reduced efficacy, dose restriction or contraindications. We expect to initiate a preclinical proof of concept study for ALLN-346 in hyperuricemia animal models in the fourth quarter of 2017. Subject to the successful outcome of this study and customary toxicology preclinical studies, we expect to file an IND for ALLN-346 in the first half of 2019.
- ***Explore collaboration opportunities for our product candidates in markets outside of the United States.*** We intend to explore collaborations to commercialize our product candidates, including ALLN-177, outside of the United States. However, depending on our evaluation of these market opportunities and the strategic merits of these collaboration opportunities, we may decide to retain commercial rights in key markets.

Competitive Strengths

We believe the following competitive strengths will help us achieve our strategy:

- Therapeutic focus on rare and severe metabolic disorders that affect the kidney and have high unmet medical needs due to the absence of approved or effective therapies;
- Lead product candidate, ALLN-177, with clear mechanism of action and consistent evidence of activity and tolerability across preclinical studies and multiple Phase 1 and 2 trials to support our planned pivotal Phase 3 program;
- Proprietary technological approach that allows us to design, formulate and deliver non-absorbed and stable enzymes orally and in sufficient doses for activity in the GI tract. This approach enables us to develop enzyme therapies that utilize the GI tract to degrade metabolites, such as oxalate and urate, reducing plasma and urine levels, and in turn, reducing their disease burden on the kidney over time;
- Management team with substantial experience in developing and commercializing pharmaceutical products for metabolic and kidney disorders;
- Strong relationships with key opinion leaders and patient advocacy groups that provide access to the industry's leading experts on hyperoxaluria and other metabolic and kidney disorders; and
- Support from leading healthcare-focused investors and board members with experience in building and operating life science companies.

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ALLN-177

Overview of Oxalate and Hyperoxaluria

Oxalate is endogenously produced as an end product of normal cellular metabolism and is also absorbed from a typical diet. Oxalate is present in many foods, especially healthy foods like plants, including green leafy vegetables, fruits and nuts, because plants utilize oxalate to store calcium. Oxalate does not have a known productive role in normal human physiology. Humans lack the innate capacity to digest oxalate, and oxalate is largely excreted unchanged by the kidney in the urine. In addition, bacteria in the GI tract, especially *Oxalobacter formigenes*, play a variable role in degrading oxalate in some patients. Progressively elevated levels of oxalate in the urine increase the risk for kidney stones and other serious kidney diseases.

Hyperoxaluria is a serious metabolic disorder characterized by markedly elevated levels of urinary oxalate excretion, due to either overproduction of oxalate by the liver from a genetic defect, called primary hyperoxaluria, or from over absorption of oxalate from the diet, called secondary hyperoxaluria. Secondary hyperoxaluria often leads to recurrent and frequent kidney stones, placing this patient population at higher risk for CKD, and end-stage renal disease, or ESRD. Secondary hyperoxaluria is further characterized either as enteric, resulting from a chronic and unremediable underlying GI disorder associated with malabsorption, or idiopathic, meaning the underlying cause is unknown. Enteric hyperoxaluria is the more severe type of secondary hyperoxaluria since the underlying GI disorder predisposes patients to chronic excess oxalate absorption. Given this hyperabsorption, patients with enteric hyperoxaluria can have levels of urinary oxalate excretion comparable to patients with primary hyperoxaluria.

The diagnosis and subsequent management of hyperoxaluria are typically based on measurements of oxalate levels in samples of urine voided and collected over a full 24 hour period, referred to as 24 hour urinary oxalate excretion. Hyperoxaluria is generally defined as levels of urinary oxalate excretion greater than 40 mg/24 hour at ages beyond infancy. While there is no firmly established level of urinary oxalate excretion that results in kidney stone formation, the scientific literature suggests that sustained urinary oxalate excretion above 30-40 mg/24 hour increases the risk of stone formation and that higher baseline urinary oxalate excretion is predictive of future stone events. Independent academic studies have shown that an increase in urinary oxalate excretion of approximately 10 mg/24 hour can increase the risk of significant adverse kidney complications. We consider severe hyperoxaluria as having levels of oxalate in the urine greater than 50 mg/24 hour. For example, the average urinary oxalate excretion level at baseline for the subjects with enteric hyperoxaluria in our most recently completed Phase 2 clinical trial was 103 mg/24 hour. Analysis of data from our clinical trials and multiple independent studies, including, but not limited to, peer-reviewed academic studies published in *Nephron* in 1980, *The New England Journal of Medicine* in 1994 and 2002, *Kidney International* in 2006 and 2008, the *Urology Journal* in 2011, the *Clinical Journal of the American Society of Nephrology* in 2016 and, most recently, *the Journal of the American Society of Nephrology Abstract Supplement* in 2017, suggest that a therapeutic strategy that reduces urinary oxalate excretion per 24 hours by approximately 20% could result in a 25-50% reduction in the incidence of kidney stone recurrence (in the short term) and may increase renal survival (in the long term).

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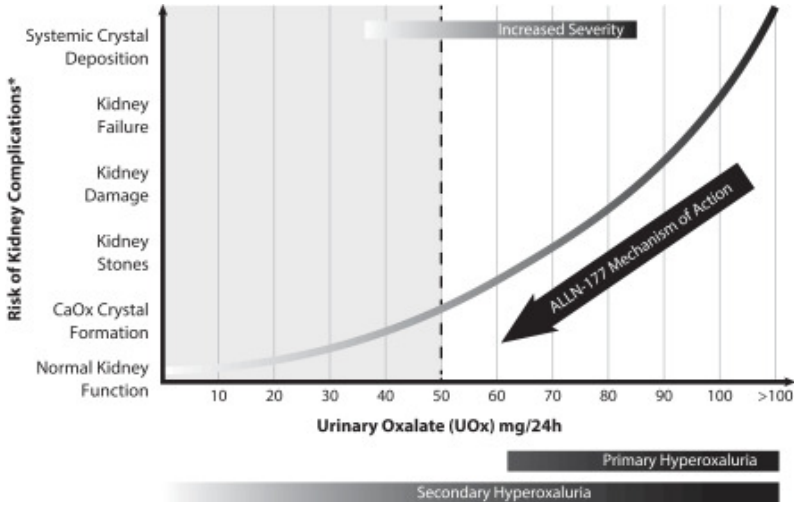
Conceptual Rendering of Hyperoxaluria and Associated Kidney Complications



* The complications noted in the figure represent a general progression of kidney harm and disease associated with increasing urinary oxalate excretion levels. Not all patients experience this progression and there is considerable variability among individuals between urinary oxalate excretion levels and kidney function and disease.

Secondary Hyperoxaluria

Secondary hyperoxaluria, or increased urinary oxalate excretion resulting from excess absorption of oxalate from the GI tract, falls into two categories:

- **Enteric**, the more severe form of secondary hyperoxaluria, which results from an underlying chronic and unremediable GI disorder; and
- **Idiopathic**, which has no known cause. Some patients with idiopathic hyperoxaluria can have severe disease characterized by hyperabsorption of oxalate with manifestations similar to enteric patients.

Enteric hyperoxaluria is most commonly seen as a complication of malabsorptive bariatric surgical procedures, such as Roux-en-Y gastric bypass, and can also be related to inflammatory bowel disease, such as Crohn's disease, or other conditions associated with GI malabsorption, including cystic fibrosis, pancreatic insufficiency, celiac disease or short bowel syndrome following surgical resection of the bowel. Enteric hyperoxaluria is the more severe type of secondary hyperoxaluria since the underlying GI disorder predisposes patients to chronic excess oxalate absorption. Given this hyperabsorption, patients with enteric hyperoxaluria can have markedly high levels of urinary oxalate excretion that can result in recurrent kidney stones, progressive calcium oxalate (CaOx) deposits in the kidney, or nephrocalcinosis, systemic oxalosis, CKD and ESRD. We estimate there are approximately 200,000 to 250,000 patients in the United States with enteric hyperoxaluria and kidney stones. We plan to target this market initially. We believe that a therapeutic agent that reduces urine oxalate levels in this population could be commercialized into a potential multi-billion dollar U.S. market without any approved therapies at present.

Idiopathic hyperoxaluria has no known underlying cause and patients with the disorder exhibit varying levels of oxalate absorption from their diet. A number of physiological parameters influence the absorption of dietary oxalate, including intestinal pH and transit time, type of diet, and the amount of other compounds and elements, such as calcium and magnesium, present in the GI tract. Consequently, a subgroup of patients with idiopathic hyperoxaluria hyperabsorbs oxalate from their diets at levels similar to those patients with enteric hyperoxaluria.

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Primary Hyperoxaluria

Primary hyperoxaluria, a type of severe hyperoxaluria, is a rare genetic disorder that can result in kidney stone disease, kidney damage, and kidney failure, which may lead to death. Primary hyperoxaluria has three main types, PH1, PH2, and PH3, with each categorization representing the particular genetic enzyme deficiency that drives the overproduction of oxalate, mainly in the liver, and massive excretion of oxalate in the urine. The most severe and common type of primary hyperoxaluria is PH1. These patients typically develop recurrent kidney stones with progressive nephrocalcinosis and end stage renal disease by 20-30 years of age. Among patients with primary hyperoxaluria, about 50 percent will have kidney failure by age 15, and about 80 percent will have kidney failure by age 30. Primary hyperoxaluria is estimated to affect approximately 1 in 58,000, or approximately 5,000 patients in the United States, and approximately 0.1 in 10,000 people, or approximately 5,000 patients in the Europe with no currently approved therapies.

Hyperoxaluria—Patient Journey and Progression of Disease

The first clinical manifestation of hyperoxaluria is often a kidney stone; however, the disorder can be variable in its presentation. Patients with severe hyperoxaluria may have recurrent kidney stones or experience infrequent or no kidney stones, yet still develop CKD and ESRD, which can be fatal. The risk for kidney stones increases with progressively elevated levels of urinary oxalate excretion. Up to 80% of kidney stones contain oxalate; therefore hyperoxaluria is a primary driver of kidney stones and reducing urinary oxalate is a scientifically targeted approach to prevent kidney stone episodes. Patients experiencing a kidney stone typically go to the emergency room for treatment due to the intense physical pain, as the kidney stone may take hours to days to pass or require interventional surgical procedures to remove it if it is too large to pass on its own. Kidney stones affect approximately 1 in 11 people in the United States at some point in their lives and the likelihood of recurrence has been estimated to be as high as 50% within 5 years of the initial event. Based on a project completed in 2016 by Health Advances, a strategic consulting firm for the healthcare industry that we engaged to conduct market research, approximately 5 million patients have been affected by recurrent calcium oxalate kidney stones in the United States.

Given the debilitating and recurrent nature of kidney stones, patients suffering from recurrent kidney stones bear significant social and financial burdens and are therefore highly motivated to prevent further relapse. Patients with enteric hyperoxaluria tend to have more frequent and more complicated kidney stone episodes and other kidney disorders as a result of their underlying GI disorders and predisposition to chronic excess oxalate absorption. For example, an additional project completed by Health Advances for us in 2017, which included analysis of peer-reviewed academic studies in two patient populations with GI malabsorption (Roux-en-Y gastric bypass and short bowel syndrome), suggested that these patients had a significantly higher kidney stone risk and rate of kidney stone recurrence than the general population of patients with kidney stones. They also had a significantly higher rate of intervention to remove kidney stones. In addition, in our largest Phase 2 clinical trial of ALLN-177 in secondary hyperoxaluria, 94% of the subjects with enteric hyperoxaluria had experienced at least one kidney stone; the enteric patients also had an average of > 3 kidney stones (> 2 mm in size) visible by routine CT scan at baseline. Based upon a separate analysis of claims data obtained from Truvan Health Analytics, part of the IBM Watson Health business, we estimate that enteric hyperoxaluria patients with new onset kidney stones, including those who have developed new onset CKD, on average incur approximately $66,000 annually in direct medical costs within a 4-year period after a malabsorptive procedure or disease diagnosis.

Further, people with kidney stones have a two times greater risk of CKD and ESRD and a higher risk of stroke and heart attack than the general population. Managing CKD and ESRD is complex as many metabolic factors, such as phosphorus, potassium and parathyroid hormone, are out of balance, often requiring treatment with multiple therapeutic agents. Patients who develop ESRD secondary to hyperoxaluria require frequent hemodialysis—approximately 6 or 7 times per week—with or without supplemental peritoneal dialysis while awaiting kidney transplantation to prevent or limit systemic oxalosis. Systemic oxalosis, which typically occurs in patients with primary or severe secondary hyperoxaluria and declining kidney function, refers to the presence

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of excess oxalate throughout the body, including the blood, bones, joints, eyes and heart. Elevated levels of oxalate in the blood is referred to as hyperoxalemia.

Patients with enteric hyperoxaluria are at risk for developing CKD, and those who receive a kidney transplant for ESRD due to oxalate-related kidney damage remain at risk for recurrent oxalate-related kidney damage. Primary and enteric hyperoxaluria patients with high urinary oxalate concentrations can develop nephrocalcinosis, which can lead to kidney failure.

Hyperoxaluria Current Treatment and Unmet Need

There is no approved pharmacologic therapy for the reduction of urinary oxalate excretion in patients with hyperoxaluria, either primary or secondary. Existing treatment options for hyperoxaluria generally are non-specific and include high fluid intake to increase urine output to more than two to three liters per day, a diet low in salt and oxalate, oral citrate and/or calcium and/or magnesium supplementation and, exclusively for the subset of responsive patients with the most severe form of primary hyperoxaluria (PH1), orthophosphate and Vitamin B6 supplementation. Despite these strategies, many patients continue to experience hyperoxaluria with recurrent kidney stones and continued risk for long-term kidney damage. Consequently, we believe patients afflicted with severe hyperoxaluria could greatly benefit from a therapy that reliably lowers oxalate levels in the body and therefore reduces the burden on the kidney to filter and then excrete the metabolite in the urine.

There are no FDA-approved therapies for enteric hyperoxaluria and no approved pharmacologic therapies specifically directed at reducing oxalate absorption driven by an underlying GI disorder. Current management of enteric hyperoxaluria relies on strategies to reduce dietary oxalate intake, increase calcium intake and drink large volumes of fluid. Increased oral fluid intake results in increased urine volume, with the goal of decreasing the saturation of oxalate in the urine and therefore reducing the risk of kidney stone formation and/or more severe kidney diseases. However, because patients with enteric hyperoxaluria have an underlying GI condition predisposing them to chronically hyperabsorb oxalate, this population often finds it particularly difficult to consistently ingest the quantities of fluid required to maintain adequate urine volume. In addition, recommendations for a low oxalate diet are somewhat in conflict with general recommendations for a healthy diet of largely plant-based foods. Many plants are high in oxalate, making it difficult to adhere to a low oxalate diet, given the relatively large number of healthy foods with moderate or high oxalate content. The limited medicinal options to treat calcium oxalate kidney stones, including thiazide diuretics and potassium citrate, have suboptimal efficacy, are not targeted to oxalate, and can be difficult to tolerate in patients with GI diseases.

We believe that ALLN-177 can address unmet medical needs for patients with severe hyperoxaluria, who experience recurrent kidney stones, CKD, end-stage renal disease and other serious kidney diseases. ALLN-177, if approved, would be the first therapeutic option that directly degrades oxalate in the GI tract using a mechanism of action specifically targeted to reducing excess absorption of oxalate.

Our Solution: ALLN-177

Our lead product candidate, ALLN-177, is a first-in-class, non-absorbed, orally-administered enzyme for the treatment of hyperoxaluria. ALLN-177, a crystalline formulation of the enzyme oxalate decarboxylase, has been designed to specifically degrade oxalate into formate and carbon dioxide within the GI tract, thus limiting systemic absorption of oxalate into the bloodstream. The decrease in systemic absorption reduces the burden on the kidney to filter and then excrete oxalate in the urine and, in turn, reduces the risk of kidney stones and other serious kidney diseases.

We are initially developing ALLN-177 for adult patients with enteric hyperoxaluria. As summarized in the table below, we have evaluated ALLN-177 in 113 subjects with secondary hyperoxaluria in three Phase 2 clinical trials, of whom 33 subjects had enteric hyperoxaluria, and a Phase 1 clinical trial with 33 healthy volunteers with

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diet-induced hyperoxaluria. Based on these data, particularly the significant reductions in urinary oxalate excretion observed in patients with enteric hyperoxaluria in our Phase 2 clinical program, we are in discussions with the FDA to finalize the design of our planned pivotal Phase 3 program. We expect to initiate the first of two Phase 3 clinical trials in the first quarter of 2018, with topline data anticipated in the second half of 2019.

In addition, the FDA has granted separate orphan drug designations for ALLN-177 for the treatment of primary hyperoxaluria and for the treatment of pediatric hyperoxaluria (primary and secondary hyperoxaluria). The European Commission has also granted orphan designation for ALLN-177 for the treatment of primary hyperoxaluria. In light of these designations, we are planning to initiate a Phase 2 clinical trial in the first quarter of 2018 in adolescents and adults with primary hyperoxaluria or severe forms of secondary hyperoxaluria, both of which can lead to systemic oxalosis, with interim data expected in the second half of 2018 and topline data anticipated in 2019.

Clinical Development Program

Overview

Since 2012, we have conducted a robust clinical development program of ALLN-177 in healthy volunteers and patients with secondary hyperoxaluria. As a result, we have developed key insights into hyperoxaluria, clinical trials in patients with hyperoxaluria and the activity and tolerability of ALLN-177 in this patient population. In our Phase 1 clinical trial in healthy volunteers, we demonstrated proof of concept that the GI tract could be used for reducing the renal oxalate burden, as measured by 24 hour urinary oxalate excretion. Our Phase 2 clinical program was designed to identify the optimal patient population, registrational endpoint and trial design for our planned pivotal Phase 3 program. In the aggregate, our clinical development program to date has demonstrated that:

- ALLN-177 can substantially reduce urinary oxalate excretion in patients with enteric hyperoxaluria;
- ALLN-177 has been well-tolerated, with no drug-related serious or severe adverse events; and
- the effect of ALLN-177 was specific to oxalate, with minimal to no changes in non-oxalate urine parameters.

The table below summarizes our clinical trial experience with ALLN-177 to date.

Trial	Trial dates	Design	N (Subjects)	Trial Population	Trial Objectives
713	August 2015 to January 2017	Phase 2, multi-center, randomized, double-blind, placebo-controlled	67	Secondary hyperoxaluria patients	Evaluate safety and efficacy of ALLN-177 to reduce urinary oxalate excretion over 28 days
396	June 2014 to December 2014	Phase 2, multi-center, open-label, single arm	16	Kidney stone formers with secondary hyperoxaluria	Evaluate safety and efficacy of ALLN-177 to reduce urinary oxalate excretion over 4 days
649	July 2015 to July 2016	Phase 2, multi-center, randomized, double-blind, placebo-controlled, crossover	30	Kidney stone formers with secondary hyperoxaluria	Evaluate safety and efficacy of 3 different doses of ALLN-177 to reduce urinary oxalate excretion over 7 days
183	May 2013 to November 2013	Phase 1, single-center, double-blind, randomized, placebo-controlled crossover	33	Healthy volunteers on a controlled high oxalate diet	Evaluate safety and efficacy of ALLN-177 over 7 days

Summary of Completed Phase 2 Clinical Trials

Study 713—Phase 2 Clinical Trial in Patients with Secondary Hyperoxaluria

We completed a multi-center, randomized, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of ALLN-177 in patients with secondary hyperoxaluria. The enrollment criteria consisted of patients with either idiopathic or enteric hyperoxaluria with at least 50 mg/24 hour in urinary oxalate, or UOx, excretion at

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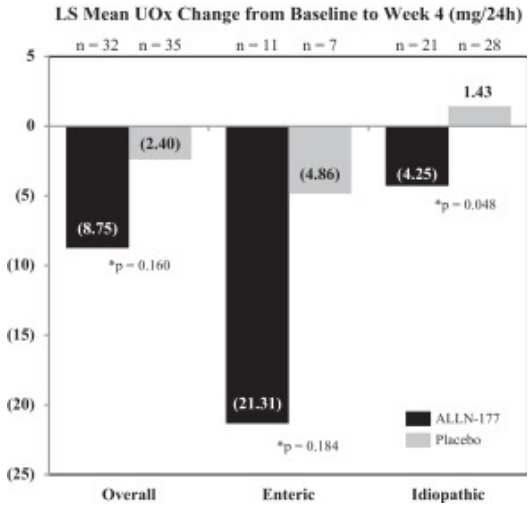
screening, most of whom had a history of kidney stones. We designed the trial to measure the ability of ALLN-177 to reduce UOx levels in this patient population, with additional planned analysis in subgroups of secondary hyperoxaluria. The primary endpoint was reduction in UOx excretion from baseline to Week 4. We specified key secondary endpoints including a measure of time-weighted average, or TWA, 24 hour UOx excretion over the four weeks of the trial and percent change in UOx excretion from baseline to Week 4. TWA 24 hour UOx excretion is the average of all 24 hour UOx excretion values obtained while on study drug (ALLN-177 or placebo), with each value weighted for the number of days since the last urine collection. We believe this measurement better captures the durability of metabolic control. We also performed various post-hoc analyses on the data.

In the trial, 71 subjects were randomized to receive either a 7,500 unit oral dose of ALLN-177 or placebo three times per day with meals, for 28 days. A total of 67 subjects received treatment (32 ALLN-177 and 35 placebo), and comprised the modified intent-to-treat and safety populations. Subjects with enteric hyperoxaluria accounted for 34% of the ALLN-177 group (11 subjects) and 20% of the placebo group (7 subjects). Subjects with idiopathic hyperoxaluria accounted for 66% of the ALLN-177 group (21 subjects) and 80% of the placebo group (28 subjects). On average, subjects with enteric hyperoxaluria had markedly higher UOx excretion levels at baseline (103 mg/24 hour) than the subjects with idiopathic hyperoxaluria (57 mg/24 hour), and despite consuming roughly half the amount of dietary oxalate as idiopathic subjects, their baseline UOx excretion levels were approximately twice as high.

Key efficacy results from this Phase 2 clinical trial included:

- In the overall population, reduction in 24 hour UOx excretion from baseline to Week 4 (the primary endpoint of the trial) was greater in subjects treated with ALLN-177 (LS mean[1] = —8.75 mg/24 hour) compared to subjects who received placebo (LS mean = —2.40 mg/24 hour); however, the difference between treatment groups (LS mean = —6.35 mg/24 hour) did not reach statistical significance (p[2] = 0.160).
  - In the subgroup with enteric hyperoxaluria, reduction in 24 hour UOx excretion from baseline to Week 4 was substantially greater in subjects treated with ALLN-177 (LS mean = —21.31 mg/24 hour) compared to subjects who received placebo (LS mean = —4.86 mg/24 hour), and the treatment difference was LS mean = —16.45 mg/24 hour (p = 0.184). The magnitude of the treatment effect was substantially greater than what was observed in the overall population.



[1] LS mean, or least squares mean, is an average calculated based on a linear model that is adjusted for other terms, such as covariates, and is less sensitive to missing data.

[2] A p-value is a conventional statistical method for measuring the statistical significance of clinical results. A p-value of 0.05 or less is generally considered to represent statistical significance, meaning that there is a less than 1-in-20 likelihood that the observed results occurred by chance.

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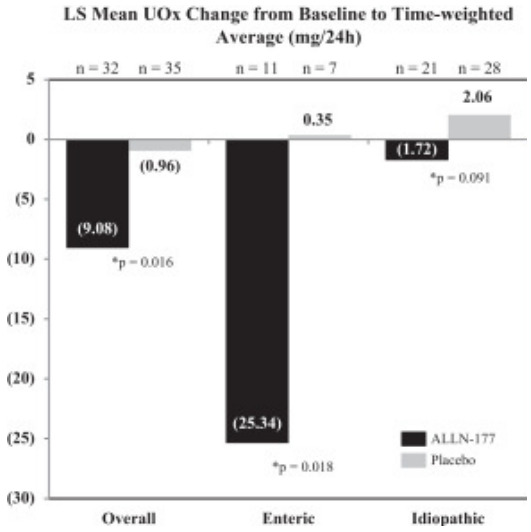
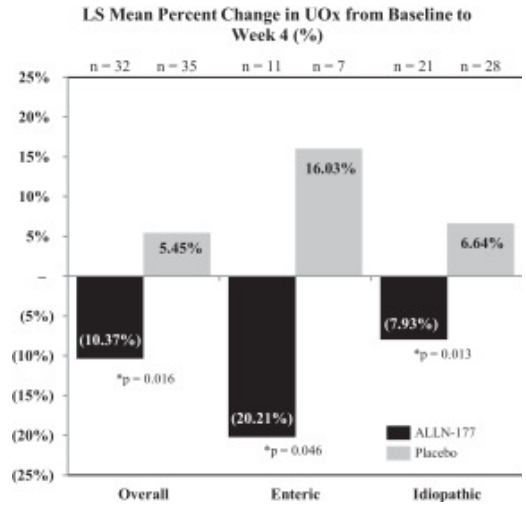
- In the overall population, reduction in 24 hour UOx excretion from baseline to TWA across Weeks 1-4 (a key pre-specified secondary endpoint of the trial) was substantially greater in subjects treated with ALLN-177 (LS mean = —9.08 mg/24 hour) compared to subjects who received placebo (LS mean = —0.96 mg/24 hour), and the difference between treatment groups was LS mean = —8.13 mg/24 hour (p = 0.016).
  - In the subgroup with enteric hyperoxaluria, reduction in 24 hour UOx excretion from baseline to TWA across Weeks 1-4 was substantially greater in subjects treated with ALLN-177 (LS mean = —25.34 mg/24 hour) compared to subjects who received placebo (LS mean = +0.35 mg/24 hour), and the treatment difference was LS mean = —25.69 mg/24 hour (p = 0.018). As with the primary efficacy endpoint, the magnitude of the treatment effect was substantially greater than what was observed in the overall population.
- In the overall population, percent reduction in 24 hour UOx excretion from baseline to Week 4 (a pre-specified secondary endpoint of the trial) was greater in subjects treated with ALLN-177 (LS mean = —10.37%) compared to subjects who received placebo (LS mean = +5.45%), and the treatment difference was LS mean = —15.81% (p = 0.016).
  - In the subgroup with enteric hyperoxaluria, percent reduction in 24 hour UOx excretion from baseline to Week 4 was substantially greater in subjects treated with ALLN-177 (LS mean = —20.21%) compared to subjects who received placebo (LS mean = +16.03%), and the treatment difference was LS mean = —36.25% (p = 0.046). The magnitude of the treatment effect was substantially greater than what was observed in the overall population.





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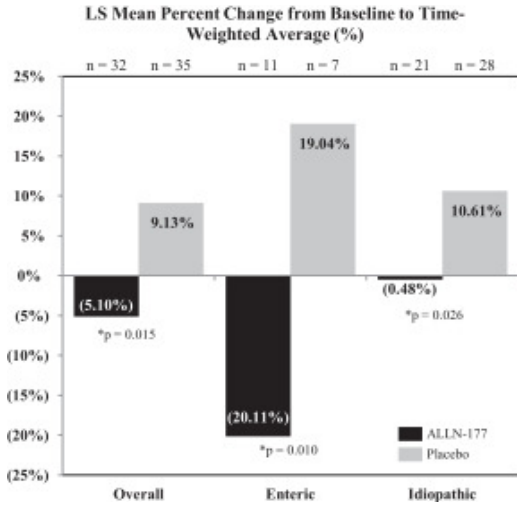
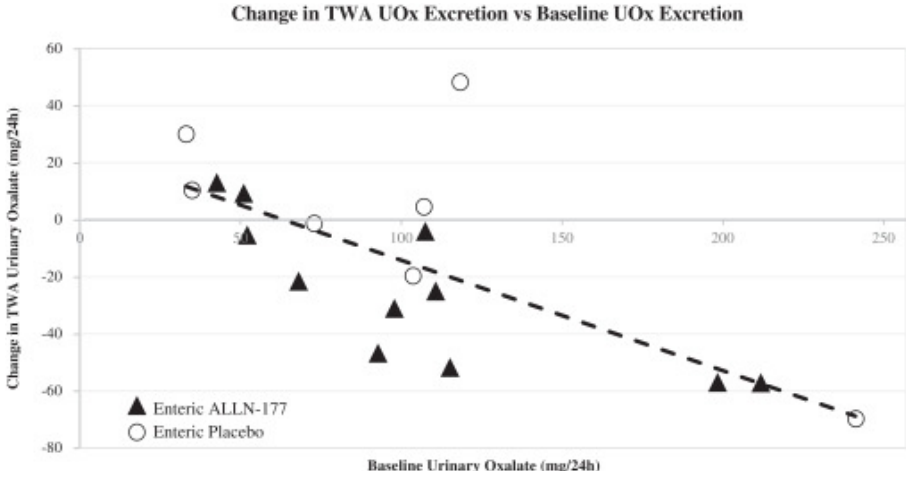
- In the overall population, percent reduction in 24 hour UOx excretion from baseline to TWA across Weeks 1-4 (a post-hoc analysis) was greater in subjects treated with ALLN-177 (LS mean = −5.10%) compared to subjects who received placebo (LS mean = +9.13%). The treatment difference was LS mean = −14.23% (p = 0.015)
  - In the subgroup with enteric hyperoxaluria, percent reduction in 24 hour UOx excretion from baseline to TWA across Weeks 1-4 was substantially greater in subjects treated with ALLN-177 (LS mean = −20.11%) compared to subjects who received placebo (LS mean = +19.04%), and the treatment difference was LS mean = −39.15% (p = 0.010). The magnitude of the treatment effect was substantially greater than what was observed in the overall population.



- In the overall population, the proportion of subjects with a ≥ 20% reduction in 24 hour UOx excretion from baseline to TWA across Weeks 1 to 4 (a post-hoc analysis) was greater in subjects treated with ALLN-177 (40.6%) compared to subjects who received placebo (8.6%), with an odds ratio[3], or OR, of 9.59 (p = 0.006).
  - In the subgroup with enteric hyperoxaluria, as illustrated by the figure below, the proportion of subjects with a ≥ 20% reduction in 24 hour UOx excretion from baseline to TWA across Weeks 1 to 4 was substantially greater in subjects treated with ALLN-177 (63.6%) compared to subjects who received placebo (14.3%), with an OR of 9.35 (p = 0.092).



[3] Odds ratio is a measure of association between an exposure and an outcome. The OR represents the odds that an outcome will occur given treatment with ALLN-177 compared to the odds of the outcome occurring in placebo subjects.

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Additional key findings:

- The trial demonstrated ALLN-177 to be well tolerated and all 32 subjects treated with ALLN-177 completed the trial. Treatment emergent adverse events, or TEAEs, were reported at a lower incidence in subjects receiving ALLN-177 (16 subjects or 50.0%) compared to subjects receiving placebo (22 subjects or 62.9%). The incidence of TEAEs that were considered related to the study drug was also lower in subjects treated with ALLN-177 (9.4%) compared with subjects who received placebo (22.9%). Among subjects with enteric hyperoxaluria, TEAEs were also reported at a lower frequency in the ALLN-177 group (6 of 11 subjects, or 54.5%) compared with the placebo group (5 of 7 subjects, or 71.4%). Similar to the overall population, GI-related TEAEs (the most common type of adverse event) were reported at a lower frequency in the ALLN-177 group (3 of 11 subjects, or 27.3%) compared with the placebo group (3 of 7 subjects, or 42.9%). While two subjects in the placebo group experienced TEAEs (nausea and dermatitis) that led to withdrawal from the trial, there were no TEAEs that led to withdrawal from the trial among the subjects treated with ALLN-177. There were no deaths, severe or serious adverse events, or SAEs, reported during the trial. There were no clinically important changes in laboratory values, vital signs or physical examinations.
- We observed intra-individual variability in UOx excretion that may have arisen from changes in diet, metabolic activity, hydration status or other factors. Consequently, we believe TWA UOx excretion per 24 hours over the study period is a clinically meaningful endpoint because it reflects the physiological effect of metabolic control of UOx excretion over time and dampens the effect of intra-individual variability in 24 hour UOx excretion. There have been several approved metabolic disease therapies that utilized a TWA measure as the endpoint for their pivotal clinical program.
- The effects of ALLN-177 were observed to be highly specific to oxalate, as there were minimal to no changes in other non-oxalate urine parameters, such as calcium, citrate, sodium and urinary volume, between baseline and Week 4 in subjects on ALLN-177.
- We observed from diet recall data that subjects with enteric hyperoxaluria consumed on average more than three meals per day and more than two snacks per day. On average, they consumed 28% of their total daily oxalate intake from snacks, with snacks accounting for 40-50% of daily oxalate intake in some subjects. In the trial, subjects received either a 7,500 unit oral dose of ALLN-177 (22,500 units/day) or placebo three times per day with meals. As a result of their eating patterns, subjects in the subgroup with enteric hyperoxaluria therefore consumed a significant portion of their daily oxalate intake without treatment. Patients with enteric hyperoxaluria often have individualized dietary patterns, particularly patients following bariatric surgery, who are typically advised to eat frequent, smaller meals. These data informed our plans to tailor the dosing regimen in our planned pivotal Phase 3 clinical program for patients with enteric hyperoxaluria in order to maximize the therapeutic effect of ALLN-177. We plan to dose subjects in our Phase 3 clinical program with 7,500 units of ALLN-177 with each meal and/or snack, up to five times per day (up to 37,500 units/day). This dosing regimen is consistent with the eating patterns of patients with enteric hyperoxaluria and is designed to provide ALLN-177 at most meals and snacks in order to maximize the degradation of oxalate ingested.

This trial was the largest randomized controlled trial ever conducted in hyperoxaluria and key elements will serve as the blueprint for our planned pivotal Phase 3 program. Although the trial did not achieve the primary efficacy endpoint, we observed substantial reductions in UOx excretion in several key pre-specified secondary endpoints, particularly in patients with enteric hyperoxaluria. Moreover, due to observed variability in UOx excretion, we believe that an analytical approach based upon TWA most appropriately indicates the therapeutic effect of ALLN-177 in patients with enteric hyperoxaluria. In addition, we observed ALLN-177 to be well tolerated and highly specific to oxalate.

Study 396—Phase 2 Clinical Trial in Patients with Secondary Hyperoxaluria

We conducted a proof of concept clinical trial in patients with secondary hyperoxaluria. This trial was a multi-center, open-label, single arm trial to evaluate the safety and efficacy of ALLN-177 treatment in 16

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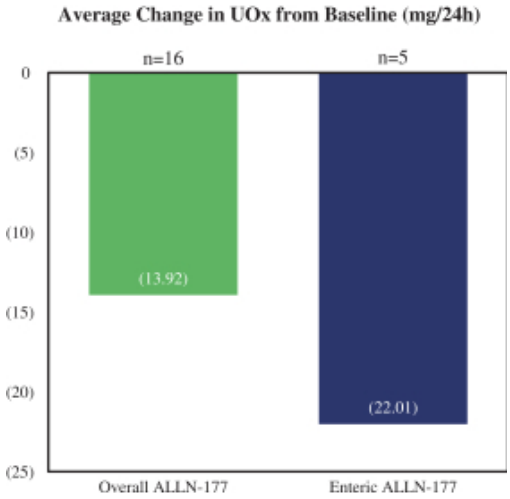
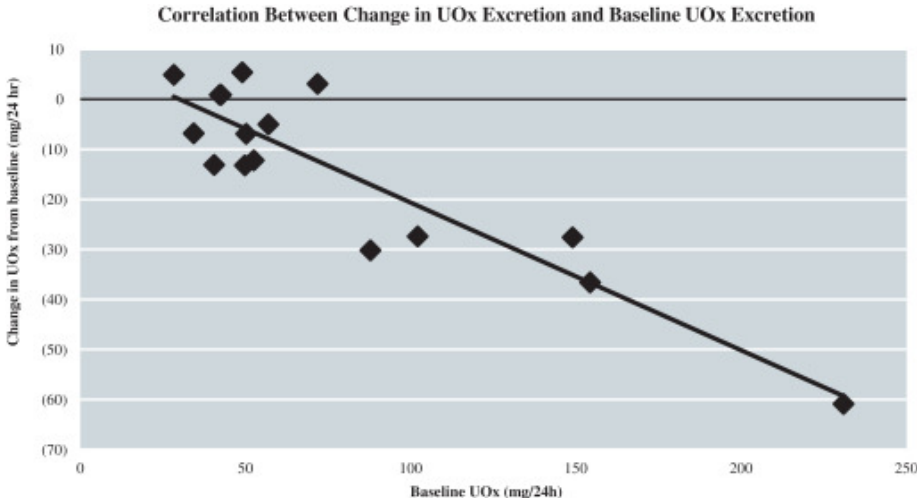
patients with secondary hyperoxaluria and kidney stones, many of whom were receiving treatment in kidney stone clinics to manage kidney stone disease (e.g. low oxalate diet and high oral fluid intake, thiazide diuretics and potassium citrate). In the trial, all subjects were treated with a 7,500 unit oral dose of ALLN-177 three times per day with meals for four days.

Key results from this Phase 2 clinical trial included:

- Subjects had an average reduction in UOx excretion of −13.92 mg/24 hour (p = 0.0084). The five subjects with enteric hyperoxaluria experienced a substantially greater average reduction in UOx excretion of −22.01 mg/24 hour as illustrated by the chart below.



- Overall, 11 of 16 subjects, or 69%, had some reduction in UOx excretion levels, in whom the mean reduction was 23%.
- The reduction in 24 hour UOx excretion was correlated with baseline UOx, demonstrating that subjects with higher UOx excretion levels at baseline showed greater reduction in UOx levels after taking ALLN-177, as shown in the figure below.



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- The trial demonstrated ALLN-177 to be well tolerated. No deaths, SAEs, or other significant adverse events occurred in this trial. No subject was withdrawn from the study due to an adverse event. There were no clinically significant hematology or serum biochemistry abnormal values reported during the trial.

Study 649—Phase 2 Clinical Trial in Patients with Secondary Hyperoxaluria

We conducted a randomized, double-blind, placebo-controlled, crossover trial with an adaptive design to evaluate the efficacy and safety of three different doses of ALLN-177 compared with placebo, administered for seven days, in subjects with kidney stones and secondary hyperoxaluria. Subjects were randomized to treatment sequences in a crossover fashion. A crossover trial is a longitudinal study in which subjects receive a sequence of different treatment arms during the course of the trial. Each treatment sequence consisted of two seven-day treatment periods separated by a seven-day washout period. Throughout the trial, each subject participated in two of the four treatment arms, which included a 1,500 unit oral dose of ALLN-177, a 3,000 unit oral dose of ALLN-177, a 7,500 unit oral dose of ALLN-177 or placebo, with meals three times a day. A total of 32 subjects were randomized; two subjects were not treated, resulting in a total of 30 subjects included in the analyses.

Randomization in the ALLN-177 low and mid-dose groups was halted after the first Adaptive Design Review Committee review of data on the first 12 subjects, resulting in only a small number of subjects in those two groups. The trial stopped enrolling in July 2016 following the second planned interim analysis once 24 subjects' data were available, due to the inability to differentiate among the treatment arms.

A post-hoc evaluation of the data was conducted to attempt to determine factors which may have influenced the inability of ALLN-177 to demonstrate a statistically significant difference from placebo. While no clear factor was identified to account for the lack of differentiation between ALLN-177 and placebo, we believe the lack of effect may have been due to variability in dietary oxalate ingestion, measurement of UOx excretion and the complexities inherent in the short-cycle, crossover study design.

All three doses of ALLN-177 were well tolerated in this study. No deaths, SAEs, or other significant AEs occurred. One subject who received the 1,500 unit oral dose of ALLN-177 per meal three times per day experienced an SAE after the seven-day washout period during the first dosing day of ALLN-177 at the 7,500 unit oral dose that led to withdrawal from the trial. The event was considered not related to study drug by the investigator. No other subjects withdrew due to a TEAE during the trial.

Summary of Planned Pivotal Phase 3 Program and Regulatory Pathway

We are in discussions with the FDA to finalize the design of our Phase 3 clinical program for ALLN-177 in adult patients with enteric hyperoxaluria. We currently expect that this pivotal program will consist of two randomized, double-blind, placebo-controlled clinical trials evaluating efficacy and safety of ALLN-177 in adult patients with enteric hyperoxaluria and UOx ≥ 50 mg/24 hours, one conducted primarily in the United States, and the other globally in the United States, Canada, Europe and potentially other geographies. We expect to enroll approximately 125 patients in the first of these two Phase 3 clinical trials, or Study 301, which trial we expect will randomize patients to four weeks of treatment with either ALLN-177 or placebo. We expect the second trial, or Study 302, will enroll approximately 400 patients and will randomize patients for a minimum of 24 weeks of treatment with either ALLN-177 or placebo. We believe that a safety database of approximately 650 subjects in our ALLN-177 development program, including approximately 400 subjects exposed to ALLN-177, including approximately 100 of whom will be exposed for 1 year, inclusive of subjects enrolled in our prior clinical trials and approximately 525 subjects expected to be enrolled in our Phase 3 program, will be sufficient to support our planned biologic license application, or BLA, assuming favorable results in our pivotal Phase 3 clinical program. Subject to further discussion with the FDA, we currently expect to initiate Study 301 in the first quarter of 2018, with topline data anticipated in the second half of 2019. Further, we currently expect to initiate Study 302 in the second half of 2018, with data available in the second half of 2020. For a discussion about the risks related to our

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planned pivotal Phase 3 clinical program, please see "Risk Factors—Risks Related to Drug Development, Regulatory Approval and Commercialization," including, but not limited to, the specific risk factors titled "We have not yet finalized the design of our pivotal Phase 3 clinical program for ALLN-177…before we can submit a BLA for this product candidate." and "We may attempt to secure approval from the FDA…withdraw accelerated approval."

In addition, we have conducted scientific advisory meetings with regulatory authorities in select countries within the European Union, in order to discuss the results of our Phase 2 clinical program, our proposed pivotal Phase 3 program as described above and potential pathways for regulatory approval of ALLN-177 in Europe. Based on these meetings, we believe that our proposed Phase 3 program, if successful, could support the filing of a future MAA application in the European Union.

Finally, the Kidney Health Initiative, or the KHI, a public-private partnership established in 2012 by the American Society of Nephrology in collaboration with stakeholders in the renal community, including the FDA, recently endorsed a project on oxalate disorders. The project called, "Identification of Appropriate Endpoints for Clinical Trials in Hyperoxaluria", was submitted by John C. Lieske, M.D., FASN, of the Mayo Clinic, in coordination with the Oxalosis and Hyperoxaluria Foundation. The Oxalosis and Hyperoxaluria Foundation is an organization dedicated to the awareness, understanding and treatment of hyperoxaluria and oxalosis for healthcare professionals, patients and their families. A stated key deliverable of the KHI project is a document that summarizes consensus recommendations regarding appropriate biochemical endpoints for clinical trials in hyperoxaluria.

Summary of Completed Phase 1 Clinical Trial—Study 183

We completed a single-center, double-blind, randomized, placebo-controlled crossover Phase 1 clinical trial to evaluate the safety and provide initial proof of concept of activity of ALLN-177 in healthy volunteers. We fed 33 healthy adult subjects an oxalate-rich diet in order to induce transient dietary hyperoxaluria. Each subject then received either a 7,500 unit oral dose of ALLN-177 or placebo three times per day with meals for seven days while continuing on the oxalate-rich diet. The high-oxalate diet increased baseline UOx excretion per 24 hours from a mean of 27.2 mg/24 hour to a mean 80.8 mg/24 hour. ALLN-177 demonstrated significantly reduced UOx excretion with a mean reduction of −11.54 mg/24 hour compared to placebo ($p = 0.0002$). The mean reduction in the 18 of 30 subjects, or 60%, defined as responders (i.e. those who had > 5 mg/24 hour reduction in UOx excretion) was −20 mg/24 hour. No deaths, SAEs, or other significant AEs occurred during this trial, and no differences in the pattern of TEAEs were observed while on ALLN-177 or placebo.

Summary of Preclinical Studies

We have completed a series of preclinical studies to assess the pharmacology and toxicology of ALLN-177. Based on the results from these studies, which demonstrated, among other things, that ALLN-177 remains in the GI tract and is not systemically absorbed, we believe the preclinical program for ALLN-177 is substantially complete.

Pharmacology Studies

We have conducted an extensive pharmacology program consisting of a total of nine rodent and pig studies of ALLN-177. Our pharmacology studies provided confirmation of our hypothesis that orally administered oxalate decarboxylase, the active enzyme in ALLN-177, can reduce or normalize UOx levels by degrading both endogenously produced and dietary oxalate in rodent and pig models of hyperoxaluria and kidney damage. The pharmacology program for ALLN-177 includes five studies in rodent models of primary and enteric hyperoxaluria (e.g. Roux-en-Y gastric bypass, or RYGB bariatric surgery) and four in pig dietary models of severe and enteric hyperoxaluria, designed to mimic these disorders in humans. Results of these preclinical studies demonstrated that ALLN-177 was well tolerated and reduced or normalized UOx excretion in a dose-dependent manner in all forms of hyperoxaluria.

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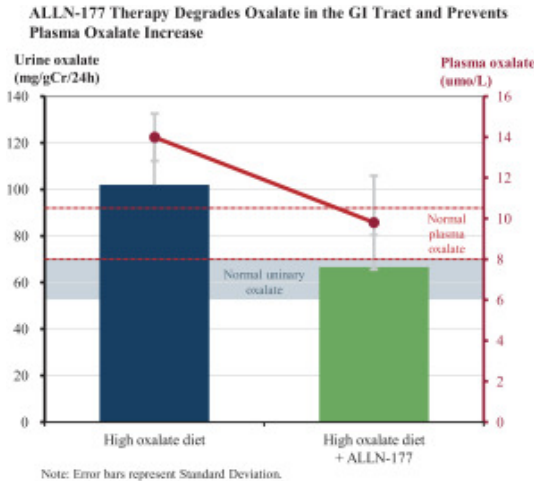
The initial pharmacology studies were completed in rodent models of primary hyperoxaluria (e.g. genetic model) and enteric hyperoxaluria (e.g. genetic and surgical models). In the primary hyperoxaluria mouse model, oxalate decarboxylase, the active enzyme in ALLN-177, was shown to be capable of acting on endogenously produced oxalate and to reduce urinary oxalate levels in a dose-dependent manner, preventing nephrocalcinosis, maintaining creatinine clearance (an important measure of kidney function) and increasing survival. In the RYGB rat model, oxalate decarboxylase reduced urine oxalate in a dose dependent manner and normalized UOx excretion.

Based on the results from testing oxalate decarboxylase in the rodent models, we and our scientific collaborators developed a pig model of hyperoxaluria to further assess the therapeutic and tolerability effects of different doses and formulations of ALLN-177, all in an effort to inform and de-risk our clinical development program in patients with hyperoxaluria. These studies were conducted in pig models of hyperoxaluria since, at the functional level, humans and pigs share many similarities with regard to kidneys, the urinary tract and the GI tract. The pig studies demonstrated that ALLN-177, administered orally with meals, reduced UOx excretion by degrading oxalate in the GI tract. Treatment was well tolerated, and resulted in mean reduction in UOx of between 12-30% relative to the control group. We observed the reduction in UOx excretion to be correlated with the severity of hyperoxaluria and treatment dose. More specifically, in a pig model where severe hyperoxaluria and hyperoxalemia were induced with an infusion of potassium oxalate salt, ALLN-177 reduced hyperoxalemia and prevented further impairment of kidney function. Finally, in a pig model where chronic dietary hyperoxaluria was induced by a human-like high oxalate diet, resulting in an above-normal increase in plasma oxalate levels, we observed that therapy with ALLN-177 normalized both plasma and urinary oxalate levels as illustrated in the figure below.



Taken together, these studies support the potential efficacy and mechanistic rationale of ALLN-177 as a novel and thus far well-tolerated treatment for reducing hyperoxaluria, hyperoxalemia, and progressive nephrocalcinosis and CKD in patients with either primary or secondary hyperoxaluria. They provide *in vivo* mechanistic confirmation that supports our proposed pivotal Phase 3 clinical program in adults with enteric hyperoxaluria and our planned Phase 2 clinical trial in adolescents and adults with primary hyperoxaluria or severe forms of secondary hyperoxaluria, both of which can lead to systemic oxalosis. In addition, these preclinical studies were submitted as scientific evidence to demonstrate the proof of concept for ALLN-177 as a treatment for primary hyperoxaluria, which led to the orphan drug designations for ALLN-177 for the treatment of primary hyperoxaluria by the FDA and the European Commission.

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Toxicology Studies

To support our clinical development program of ALLN-177, we conducted a total of six toxicity studies in rats and dogs. These studies demonstrated that ALLN-177 was well tolerated in animals. We conducted our first two studies which demonstrated that oral administration of ALLN-177 for 14 days was well tolerated in animals at doses up to 200 mg/kg/day (which corresponds to 2,000 units/kg/day). We also performed an additional 2-week repeated dose toxicology study of ALLN-177 in rats at doses up to 4,860 units/kg/day, approximately 13 times the dose used in our Phase 1 clinical trial of ALLN-177, for a 60 kg subject.

To support clinical trials of longer duration, we conducted two 28-day repeat-dose toxicology studies in rats and dogs. These studies demonstrated that twice-daily oral administration of ALLN-177 was well tolerated for 28 consecutive days at 520 mg/kg/day. The NOAEL, or no-observed-adverse-effect-level, or highest concentration of drug which caused no detectable adverse effect, was 7,000 units/kg/day in both species. This concentration was approximately 18 times the highest dose used in Study 713, our 28-day Phase 2 clinical trial, for a 60 kg subject.

We have also completed a six month chronic toxicology study of ALLN-177 in rats. It demonstrated that twice-daily oral administration of ALLN-177 was well tolerated for 26 consecutive weeks at 520 mg/kg/day (6,618 units/kg/day) with the NOAEL approximately 11 times greater for a 60 kg subject than we expect to use in our planned pivotal Phase 3 clinical program. In each study, the NOAEL was the highest dose evaluated in that particular study.

Based on the results from these studies, which demonstrated, among other things, that ALLN-177 is not systemically absorbed, and feedback from the FDA, we believe the preclinical program for ALLN-177 is substantially complete, and no carcinogenicity, genotoxicity, or reproductive toxicity studies are planned.

In connection with our preparations for our planned pivotal Phase 3 clinical program, we are considering the best mechanism to study the potential for drug-drug interactions in patients treated with ALLN-177 and also the potential effects of formate generation resulting from ALLN-177's degradation of oxalate. Based on feedback from the FDA, we plan to conduct an *in vitro* assessment to evaluate the potential for systemic drug interactions. Based on extensive scientific evidence, we believe that the level of formate generation derived from ALLN-177 and oxalate is below limits generally regarded as safe. We are developing a plan to investigate these two items. The nature of additional studies, if any, will be determined by the results of these initial investigations.

Summary of Planned Phase 2 Clinical Program for ALLN-177 in Primary and Severe Hyperoxaluria

Our preclinical pharmacology studies in models of primary hyperoxaluria have demonstrated that ALLN-177 significantly reduced oxalate levels in the urine and plasma. The FDA has granted separate orphan drug designations for ALLN-177 for the treatment of primary hyperoxaluria and for the treatment of pediatric hyperoxaluria (primary and secondary hyperoxaluria). The European Commission has also granted orphan designation for ALLN-177 for the treatment of primary hyperoxaluria. In light of these designations, we are planning to initiate a Phase 2 clinical trial in the first quarter of 2018 in adolescents and adults with primary hyperoxaluria or severe forms of secondary hyperoxaluria, both of which can lead to systemic oxalosis, with interim data expected in the second half of 2018 and topline data anticipated in 2019.

Systemic oxalosis refers to the presence of excess oxalate throughout the body, including the bones, joints, eyes and heart, which occurs when the kidney fails to excrete oxalate from the body, leading to elevated oxalate levels in the blood and deposition in the tissues. Our planned Phase 2 clinical trial will utilize an open-label basket trial design with a 12-week treatment period and will enroll subsets of patients suffering from complications of severe hyperoxaluria, including adults and adolescents with primary hyperoxaluria or enteric hyperoxaluria. More specifically, we plan to enroll subjects ≥12 years of age with primary or enteric hyperoxaluria, approximately 50% each, screened for baseline UOx excretion greater than 40 mg/24 hr and

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plasma oxalate levels greater than 5 µmol/L. Since these patients typically have varying degrees of renal impairment, such as CKD, dialysis patients will be allowed, but limited to approximately 25% of total enrollment as extensive tissue oxalate deposition may obscure a potential signal of lowering plasma oxalate levels. We expect that the endpoints will include change from baseline in plasma oxalate and UOx excretion. A peer-reviewed study published in the *New England Journal of Medicine* in 1994 demonstrated that treatment with orthophosphate and Vitamin B6 in a subset of patients with primary hyperoxaluria reduced UOx excretion by approximately 10% annually over 10 years, which showed preservation of renal function in these patients. In light of this data, we believe that the ability of ALLN-177 to degrade oxalate in the GI tract to prevent systemic oxalate absorption and therefore decrease the renal oxalate burden is well suited for testing in this patient populations. If ALLN-177 can reduce urine and plasma oxalate levels in these patients, it may be able to diminish the amount of systemic oxalate available for calcium oxalate crystal formation and deposition in the kidney and other organs or tissues.

Other Potential Indications for ALLN-177—Idiopathic Hyperoxaluria

We believe the mechanism of action of ALLN-177, which is designed to degrade oxalate in the GI tract, is particularly well-targeted to treat enteric hyperoxaluria where excess oxalate absorption is driven by an underlying GI disorder. While hyperabsorption of oxalate is typically a characteristic of enteric hyperoxaluria, we believe there is a subgroup of patients with idiopathic hyperoxaluria that hyperabsorbs oxalate from their diets at levels similar to those patients with enteric hyperoxaluria. We confirmed these pathophysiological traits in both enteric and idiopathic patients in a prospective controlled clinical trial designed to identify patients who hyperabsorb oxalate (Study 204) in 22 patients with secondary hyperoxaluria, with no study drug administration. Although subjects with enteric hyperoxaluria had greater average oxalate absorption than the subjects with idiopathic hyperoxaluria, approximately 40% of the subjects with idiopathic hyperoxaluria approached absorption levels observed in subjects with enteric disorders. Consequently, although we are initially targeting ALLN-177 for patients with enteric hyperoxaluria, we believe the product candidate holds promise in treating the subset of patients with idiopathic hyperoxaluria who hyperabsorb oxalate.

ALLN-346

Overview of Hyperuricemia & Gout

Hyperuricemia, or elevated levels of uric acid in the blood, results from overproduction or insufficient excretion of urate, or often a combination of the two. Humans lack urate oxidase, an enzyme that degrades uric acid in a wide range of other organisms, including animals, plants, bacteria and fungi. Hyperuricemia can be a predisposing condition for gout and kidney stones, and is also intricately linked with various metabolic disorders, including hypertension, CKD, glucose intolerance, dyslipidemia, insulin resistance and obesity. Hyperuricemia may also be an independent risk factor for cardiovascular disease.

Gout is a kind of arthritis caused by excess uric acid in the blood. When uric acid levels in the blood are too high, hard crystals may form in the joints, causing attacks of sudden burning pain, stiffness, and swelling. These attacks can happen over and over unless gout is treated. Over time, they can harm joints, tendons, and other tissues.

Current Therapeutic Options and Their Limitations

The gout market is incompletely served by existing therapies. Several of the current drugs approved for gout raise concerns over lack of efficacy or increased toxicity in patients with reduced kidney function. There are approximately 850,000 hyperuricemia patients with moderate to severe CKD on urate lowering therapy of which approximately 375,000 have uncontrolled gout. Hyperuricemic and gout patients with renal impairment are more challenging to manage due to limitations of existing therapies. These limitations include poor tolerability, reduced efficacy, dose restriction and contraindications. Co-morbidities (e.g. cardiovascular disease) are common in this patient population and may also limit urate lowering therapeutic options. Accordingly, there is a significant unmet need for a safe and effective therapy that can be used in patients with renal impairment.

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Our Solution

Our second product candidate, ALLN-346, is designed to be a first-in-class, orally-administered non-absorbed urate-degrading enzyme. ALLN-346 is a recombinant, mutant formulation of urate oxidase designed to be active in humans and have greater stability and/or activity than naturally occurring enzymes. We have developed ALLN-346 to degrade urate in the GI tract and in turn, reduce the urate burden on the impaired kidney and lower the risk of urate related complications, including gouty flares and arthritis and urate-based stones in the kidney, bladder and/or urinary tract. We are initially targeting ALLN-346 for patients with hyperuricemia and moderate to severe CKD, where currently available therapeutics are insufficient. Data from prior animal studies of an unmodified urate oxidase enzyme demonstrated normalization of plasma uric acid similar to allopurinol, a drug commonly prescribed for gout patients. We expect to initiate a preclinical proof of concept study for ALLN-346 in hyperuricemia animal models in the fourth quarter of 2017. Subject to the successful outcome of this study and other customary toxicology preclinical studies, we expect to file an IND for ALLN-346 in the first half of 2019.

Our Proprietary Technological Approach

Expertise in Enzyme Technology

We believe our proprietary know-how in enzyme technology allows us to design, formulate and deliver non-absorbed and stable enzymes orally and in sufficient doses for activity in the GI tract. This approach enables us to develop enzyme therapies that degrade metabolites, such as oxalate and urate, within the GI tract, thereby preventing their absorption, which reduces potentially toxic metabolite levels in the blood and urine, and in turn, diminishes the disease burden on the kidney over time.

One of the technologies that we use in our lead product candidate, ALLN-177, is protein crystallization, which stabilizes a highly active form of the oxalate degrading enzyme, oxalate decarboxylase, ensuring effective transit through the GI tract, as well as stabilization at room temperature for convenient storage. Crystallized enzymes are more stable, pure and concentrated than enzymes in solution. For example, one enzyme crystal may contain several billion molecules of the underlying enzyme. These characteristics improve storage and delivery, permitting delivery of the enzyme molecules with fewer capsules. Once an enzyme is in the crystallized state, we can formulate it for oral delivery. Within the GI tract, the crystalized enzyme is stable and protected from proteolytic degradation, yet sufficiently porous for metabolites to pass through and be degraded by the enzyme. The general therapeutic approach of deploying a non-absorbed drug into the GI tract to reduce metabolic disease burden in patients with kidney disease has been proven successful in several therapeutic categories. For example, Renagel and Renvela, marketed by Sanofi, remove excess levels of phosphate in the body in patients with CKD by delivering drug to the GI tract, where it binds to phosphate and removes it from the body through the bowel.

Our knowledge base from ALLN-177 provides us with a useful template for our other research and preclinical programs that rely on the same fundamental science and therapeutic strategy. We anticipate that our second product candidate, ALLN-346, a first-in-class uricase enzyme, will utilize several proprietary technologies to ensure its stabilization in the GI tract as well as other attractive manufacturing, clinical and commercial attributes similar to ALLN-177.

Manufacturing

ALLN-177 is an oral, solid dosage form of crystalline recombinant oxalate decarboxylase enzyme that is produced using a combination of traditional and novel manufacturing processes. The methods of production for ALLN-177 have been carefully selected for cost-effectiveness and ease of scaling. We believe our manufacturing technology enables us to produce large quantities of our oral enzyme product candidates, sufficiently to support our clinical and commercial strategy, with costs anticipated to be comparable to small molecule therapeutics. Working in collaboration with top-tier development and manufacturing companies, we have completed several successive scale-ups to the manufacturing process in support of increasing clinical trial demand and in planning for commercialization.

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Manufacturing biologic drugs is generally a complex and cost intensive process because they are manufactured in living systems or cells and tend to be large complex molecules. Since the living systems used to produce biologics can be sensitive to minor changes in manufacturing techniques, small process differences can significantly affect the nature of the finished biologic and, most importantly, the way it functions in the body.

Production of ALLN-177 occurs utilizing scientifically developed know-how, delivering high productivity from host bacterial cells. The entire biomass is harvested and processed through primary recovery and downstream purification unit operations, resulting in the recovery of large quantities of oxalate decarboxylase. The purified and concentrated product is crystallized, dried into a protein powder and formulated for production as an oral capsule. The oral capsule presentation has attractive properties of pharmaceutical activity and stability suitable for further development and ultimate commercial use. Over the course of our development of ALLN-177, we have been able to increase enzyme yield and activity through improvements to our manufacturing processes, thereby reducing the pill burden of our therapeutic candidate. As a result, we expect that the dosing regimen for our planned pivotal Phase 3 program will be one to two capsules per dosing compared to five capsules per dosing in our Phase 2 clinical program.

Drug product production starts with dried oxalate decarboxylase crystals, then uses tailored pharmaceutical techniques to blend, densify and encapsulate the product candidate, which is an oral, solid-dose formulation of the crystallized enzyme. We have secured development and supply agreements with premiere global drug product contract manufacturing organizations suited to meet the needs of commercialization for ALLN-177. Finally, we forecast cost of goods sold for ALLN-177 to be comparable to traditional oral small molecules over the course of its commercialization life cycle.

Commercialization Strategy

We hold worldwide commercialization and development rights to all of our first-in-class, oral, non-absorbed enzyme therapeutic product candidates. The FDA has granted separate orphan drug designations for our lead product candidate, ALLN-177, for the treatment of primary hyperoxaluria and for the treatment pediatric hyperoxaluria (primary and secondary hyperoxaluria). In addition, the European Commission has granted orphan designation for ALLN-177 for the treatment of primary hyperoxaluria.

ALLN-177, if approved, has the potential to be the first therapeutic option for patients with severe hyperoxaluria. We intend to independently pursue regulatory approval of ALLN-177 in patients with enteric hyperoxaluria in the United States and, if approved, to commercialize the product by building a focused commercial organization in the United States specifically to target nephrologists and urologists who treat patients with hyperoxaluria, particularly at kidney stone clinics. In addition, we plan to build a marketing organization that will conceive and implement marketing strategies for any product that we directly commercialize. The responsibilities of the marketing organization would include developing commercialization initiatives for each approved product and establishing and maintaining relationships with researchers, practitioners and key opinion leaders for rare and severe metabolic and kidney disorders.

Outside of the United States, we intend to explore collaborations to commercialize our product candidates, including ALLN-177. Depending on our evaluation of these market opportunities and the strategic merits of these collaboration opportunities, we may decide to retain commercial rights in key markets.

Competition

Our industry is highly competitive and subject to rapid and significant technological change as researchers learn more about diseases and develop new technologies and treatments. Our potential competitors include primarily large pharmaceutical, biotechnology companies and specialty pharmaceutical companies. Key competitive factors affecting the commercial success of ALLN-177, ALLN-346 and any other product candidates we may develop are likely to be efficacy, safety and tolerability profile, reliability, convenience of administration, price and reimbursement.

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There is no approved pharmacologic therapy for the reduction of urinary oxalate excretion in patients with hyperoxaluria, either primary or secondary. Existing treatment options for hyperoxaluria generally are non-specific and include high fluid intake to increase urine output to more than two to three liters per day, a diet low in salt and oxalate, oral citrate and/or calcium and/or magnesium supplementation and orthophosphate and Vitamin B6, exclusively for the specific subset of responsive patients with the most severe form of primary hyperoxaluria (PH1).

We are aware of other companies pursuing oxalate reduction in both primary and secondary hyperoxaluria. Alnylam and Dicerna are developing injectable gene-silencing technologies using RNA, with product candidates focused on addressing primary hyperoxaluria. Both are in early-stage clinical development. Oxthera AB (Sweden) and Captozyme (U.S.) are developing orally delivered products to degrade oxalate in the stomach and GI tract. Oxthera is advancing Oxabact, *Oxalobacter formigenes*, into Phase 3 clinical trials for the treatment of primary hyperoxaluria.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patents intended to cover the composition of matter of our product candidates, their methods of use and processes for their manufacture, and any other aspects of inventions that are commercially important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

We plan to continue to expand our intellectual property estate by filing patent applications directed to compositions, methods of treatment, dosage forms, and dosage regimens that we identify during the course of our business. Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and patent scope can be reinterpreted by the courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any or our issued patents will provide sufficient protection from competitors. Any of our patents may be challenged, circumvented, or invalidated by third parties.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings or derivation proceedings declared by the U.S. Patent and Trademark Office, or the USPTO, to determine priority of invention.

Patents

As of July 25, 2017, we own or have rights in 4 issued U.S. patents, 15 issued foreign patents, 4 pending U.S. patent applications, and 7 pending foreign patent applications.

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With regard to ALLN-177, we have exclusively licensed from Althea Technologies, Inc. (now known as Ajinomoto Althea, Inc.), or Althea, one issued U.S. patent with method of use claims directed to the reduction of oxalate in a mammal by orally administering a composition containing uncrosslinked oxalate decarboxylase crystals, which is scheduled to expire in 2027, without taking a potential patent term extension into account. This U.S. patent belongs to a family of patents and includes a granted European patent, which has been validated in a number of countries including Denmark, France, Germany, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, Switzerland, and the UK; and patent applications pending in Canada and China. This patent family also includes a U.S. patent with method of use claims directed to a method of reducing oxalate with oxalate decarboxylase crystals in an extracorporeal device, which is scheduled to expire in 2027, without taking a potential patent term extension into account.

In addition, we own one pending U.S. application with composition of matter claims directed to a pharmaceutical composition comprising biologically active uncrosslinked oxalate decarboxylase crystals, which, if granted, would be scheduled to expire in 2027, without taking a patent term extension into account. We also own one U.S. patent with composition of matter claims directed to a capsule containing crystals of spray-dried oxalate decarboxylase, which is scheduled to expire in 2034, without taking a potential patent term extension into account.

Another family of patent applications that we own are pending in the U.S., Canada, Europe, Israel and Japan with composition of matter claims directed to a composition comprising a peritoneal dialysis solution and uncrosslinked crystals of oxalate decarboxylase for use in reducing oxalate during a dialysis-based treatment, which, if granted, would be scheduled to expire in 2034, without taking a patent term extension into account.

With regard to ALLN-346, we own a U.S. provisional patent application with composition of matter claims directed to novel recombinant uricase enzymes and method of use claims directed to treating certain diseases associated with elevated levels of uric acid with such enzymes. A U.S. patent claiming the benefit of the provisional application, if issued, would be expected to expire in 2038, without taking a patent term extension into account.

In the United States, the term of a patent covering an FDA-approved drug may be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years beyond the expiration of the patent, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. For example, it is possible that an issued U.S. patent covering ALLN-177 or its use may be entitled to a patent term extension. If ALLN-177 receives FDA approval, we intend to apply for a patent term extension, if available, to extend the term of a patent that covers the approved product. We also intend to seek patent term extensions in any jurisdictions where they are available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

In addition to patent protection, we also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, certain aspects of our manufacturing procedures. However, trade secrets can be difficult to protect. Although we take steps to protect our proprietary information, including restricting access to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors and potential collaborators, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

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Althea License Agreement

In March 2012, we entered into a license agreement with Althea, as amended in March 2016, pursuant to which Althea granted us an exclusive, worldwide, royalty-bearing, sublicensable license under specified intellectual property rights relating to, among other things, oxalate decarboxylase and ALTU-237, now called ALLN-177, to develop, use, make, have made, market, offer to sell, sell, have sold, distribute, import or otherwise exploit licensed products. Althea expressly retains all rights under the licensed patents that are not granted to us under the agreement, which we refer to as Althea's retained rights. We have the right to sublicense our licensed rights, provided that each sublicense agreement must be in writing and consistent with the terms of the license agreement. We are obligated to use commercially reasonable efforts to develop and commercialize the licensed products for the treatment of hyperoxaluria.

Under the license agreement, we reimbursed Althea for patent-related fees and costs totaling $0.1 million in the aggregate and have issued to Althea a total of 88,186 shares of our common stock. Althea is entitled to receive regulatory milestone payments totaling up to $31.0 million in the aggregate. We are also obligated to make additional payments to Althea of up to an aggregate of $25.0 million based upon the occurrence of certain sales milestones. Althea is entitled to receive mid-single-digit percentage royalties on net sales of licensed products, made by us, our affiliates, or our sublicensees, subject to certain reductions for any royalty payments required to be made by us to acquire patent rights, however, such royalty payments cannot be reduced below an aggregate minimum floor. The milestone payments are not creditable against royalties. The royalty term will expire on a licensed product-by-licensed product and country-by-country basis upon the later of the expiration of the last-to-expire valid patent claim that covers the composition, manufacture, or use of such licensed product in such country, or the tenth anniversary of the date of the first commercial sale of such licensed product in such country.

We have the first right, but not the obligation, to prosecute, defend, maintain and enforce certain product-specific patent rights licensed under the agreement, and Althea has the exclusive right to prosecute, defend, maintain and enforce all other licensed patent rights. If we are controlling any lawsuits regarding the licensed patents, we cannot enter into a settlement without the prior written consent of Althea. Any sums recovered in such lawsuits will be shared between us and Althea. Unless terminated earlier, the term of the license agreement will expire on date of the last-to-expire royalty term. We have the right to terminate the agreement for convenience upon 60 days prior written notice to Althea. Either party may terminate the agreement after a 60-day notice period in the event of an uncured material breach by the other party. If we terminate the agreement for convenience or if Althea terminates the agreement for cause, we grant Althea a right of first negotiation, exercisable for the 30-day period after such termination, to obtain an exclusive license to certain patent rights and data controlled by us that are related to the licensed products and to have all investigational new drug applications, or INDs (other than the IND for ALLN-177), transferred to Althea.

In addition, pursuant to a letter agreement we entered into with Althea in June 2017, and subject to a fully paid-up exclusive worldwide license that we grant to Althea with respect to Althea's retained rights, Althea assigned certain U.S. patent rights to us. We agreed to continue to comply with our obligations under the license agreement, including our obligation to make milestone and royalty payments to Althea. Upon any termination or expiration of the license agreement, we are obligated to assign such patent rights back to Althea.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products, including biological products. In addition, some jurisdictions regulate the pricing of pharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

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Licensure and Regulation of Biologics in the United States

In the United States, our candidate products are regulated as biological products, or biologics, under the Public Health Service Act, or PHSA, and the Federal Food, Drug, and Cosmetic Act, or FDCA, and their implementing regulations. The failure to comply with the applicable U.S. requirements at any time during the product development process, including nonclinical testing, clinical testing, the approval process or post-approval process, may subject an applicant to delays in the conduct of a study, regulatory review and approval, and/or administrative or judicial sanctions. These sanctions may include, but are not limited to, the U.S. Food and Drug Administration's, or FDA's, refusal to allow an applicant to proceed with clinical testing, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, and civil or criminal investigations and penalties brought by the FDA or the Department of Justice, or DOJ, or other governmental entities.

An applicant seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps:

- nonclinical laboratory tests, animal studies and formulation studies all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency, and purity of the product candidate for each proposed indication, in accordance with Good Clinical Practices, or GCP;
- preparation and submission to the FDA of a Biologic License Application, or BLA, for a biologic product requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods, and controls are adequate to preserve the product's identity, strength, quality, and purity;
- satisfactory completion of any FDA audits of the nonclinical and clinical study sites to assure compliance with GLPs and GCPs, respectively, and the integrity of clinical data in support of the BLA;
- payment of user fees and securing FDA approval of the BLA and licensure of the new biologic product; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any post-approval studies required by the FDA.

Nonclinical Studies and Investigational New Drug Application

Before testing any biologic product candidate in humans, the product candidate must undergo nonclinical testing. Nonclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as animal studies to evaluate the potential for efficacy and toxicity. The conduct of the nonclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of

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the nonclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the trial to commence or allowing the trial to commence on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. This order issued by the FDA would delay either a proposed clinical study or cause suspension of an ongoing study, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigation may proceed. This could cause significant delays or difficulties in completing planned clinical trials in a timely manner. The FDA also may impose clinical holds on a biologic product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

Human Clinical Trials in Support of a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of a qualified principal investigator in accordance with GCP requirements. Clinical trials are conducted under study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of the BLA so long as the clinical trial is well-designed and well-conducted in accordance with GCP, including review and approval by an independent ethics committee, and the FDA is able to validate the study data through an onsite inspection, if necessary.

Further, each clinical trial must be reviewed and approved by an institutional review board, or IRB, either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, and the safety of human subjects. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated check points based on access to certain data from the study.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- *Phase 1* clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion, and pharmacodynamics in healthy humans or, on occasion, in patients, such as cancer patients.

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- *Phase 2* clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.
- *Phase 3* clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to further evaluate dosage, provide substantial evidence of clinical efficacy, and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a biologic; such Phase 3 studies are referred to as "pivotal."

In some cases, the FDA may approve a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

Compliance with cGMP Requirements

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Manufacturers may have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Review and Approval of a BLA

The results of product candidate development, nonclinical testing, and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting license to market the product. The BLA must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether it is sufficient to accept for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act,

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or the PDUFA, the FDA has ten months in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of the application. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure, and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure, and potent.

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of nonclinical and clinical study sites to assure compliance with GLPs and GCPs, respectively, the FDA may issue an approval letter, denial letter, or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. If the application is not approved, the FDA may issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. Such resubmissions are classified under PDUFA as either Class 1 or Class 2. The classification of a resubmission is based on the information submitted by an applicant in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has two months to review a Class 1 resubmission and six months to review a Class 2 resubmission. The FDA will not approve an application until issues identified in the complete response letter have been addressed. The FDA issues a denial letter if it determines that the establishment or product does not meet the agency's requirements.

The FDA may also refer the application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved. In particular, the FDA may refer applications for novel biologic products or biologic products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates, and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may limit the approved indications for use of the product. It may also require that contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

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Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast track designation, breakthrough therapy designation, and priority review designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case- by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is

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not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

The 21st Century Cures Act

The 21st Century Cures Act, which was signed into law in December 2016, requires the FDA to establish a process for the qualification of drug development tools that may be used to support or obtain licensure of a biological product or support of the investigational use of a biological product. A drug development tool includes a biomarker, a clinical outcome assessment, and any other method, material, or measure that the FDA determines aids drug development and regulatory review. A biomarker is a characteristic, such as a physiologic, pathologic, or anatomic characteristic or measurement, that is objectively measured and evaluated as an indicator of normal biological processes, pathologic processes, or biological responses to a therapeutic intervention and includes a surrogate endpoint. A clinical outcome assessment is a measurement of a patient's symptoms, overall mental state, or the effects of a disease or condition on how the patient functions and includes a patient-reported outcome.

The 21st Century Cures Act also requires that, for approval of any BLAs submitted after June 12, 2017, the FDA shall make public a brief statement regarding the patient experience data and related information, if any, submitted and reviewed as part of the application. Patient experience data includes data that are collected by any persons, including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers and drug manufacturers, and are intended to provide information about patients' experiences with a disease or condition, including the impact of such disease or condition, or a related therapy, on patients' lives and patient preferences with respect to treatment of such disease or condition.

Post-Approval Regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all regular post-approval regulatory requirements as well as any post-approval requirements that the FDA has imposed as part of the approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and

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certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A biologic product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency, and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled letters or warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Orphan Drug Designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the biologic for the disease or condition will be recovered from sales of the product in the United States. The FDA has granted Orphan Drug Designation to ALLN-177 for the treatment of primary hyperoxaluria and pediatric hyperoxaluria. This includes both children with secondary hyperoxaluria, attributable to excess GI absorption of oxalate, as well as the rare condition primary hyperoxaluria, a genetic defect of one of several liver enzymes.

Orphan drug designation qualifies a company for tax credits and market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA. An application for designation as

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an orphan product can be made any time prior to the filing of an application for approval to market the product. A product becomes an orphan when it receives orphan drug designation from the Office of Orphan Products Development, or OOPD, at the FDA based on acceptable confidential requests made under the regulatory provisions. The product must then go through the review and approval process like any other product.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Biosimilars and Exclusivity

The Affordable Care Act, which was signed into law in March 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA established a regulatory scheme

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authorizing the FDA to approve biosimilars and interchangeable biosimilars. To date, four biosimilar products have been approved by the FDA for use in the United States. No interchangeable biosimilars, however, have been approved. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Additional guidances are expected to be finalized by the FDA in the near term.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own nonclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

Patent Term Restoration and Extension

A patent claiming a new biologic product may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, which permits a patent restoration of up to five years for patent term lost during product development and FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of an IND and the submission date of a marketing application, plus the time between the submission date of a marketing application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company also must comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union, or EU, generally follows the same lines as in the United States. It entails satisfactory completion of nonclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the EU.

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Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the EU has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of an EU member state in which the clinical trial is to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion. The clinical trial application, or CTA, must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents.

In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It is expected that the new Clinical Trials Regulation (EU) No 536/2014 will apply in 2019 with a three-year transition period. It will overhaul the current system of approvals for clinical trials in the EU. Specifically, the new regulation, which will be directly applicable in all member states, aims at simplifying and streamlining the approval of clinical trials in the EU. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single entry point and strictly defined deadlines for the assessment of clinical trial applications.

Marketing Authorization

To obtain a marketing authorization for a product under the EU regulatory system, an applicant must submit an MAA, either under a centralized procedure administered by the European Medicines Authority, or EMA, or one of the procedures administered by competent authorities in EU Member States (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the EU. Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the EU, an applicant must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver, or a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting an initial assessment of a product. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

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Regulatory Data Protection in the European Union

In the European Union, new chemical entities approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Regulation (EC) No 726/2004, as amended, and Directive 2001/83/EC, as amended. Data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for a period of eight years. During the additional two-year period of market exclusivity, a generic marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, nonclinical tests and clinical trials.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing member state. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the drug on the EU market (in the case of the centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

Regulatory Requirements after Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the EU's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the EU, which mandate the methods, facilities, and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended.

Orphan Drug Designation and Exclusivity

Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the EU when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug will be of significant benefit to those affected by that condition.

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An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance, and the possibility to apply for a centralized EU marketing authorization. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

Coverage, Pricing, and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may seek regulatory approval by the FDA or other government authorities. In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. Even if any product candidates we may develop are approved, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers, and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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Outside the United States, ensuring adequate coverage and payment for any product candidates we may develop will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of any product candidates we may develop to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular product candidate to currently available therapies (so called health technology assessments, or HTAs) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. E.U. member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade (arbitrage between low-priced and high-priced member states), can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Arrangements with providers, consultants, third-party payors, and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to physicians and teaching physicians and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; making a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or

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attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

By way of example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In March 2010, the United States Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for products under government health care programs. Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;

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- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable products to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient products to be covered under Medicare Part D;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- the Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products. The ACA provided that under certain circumstances, IPAB recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings; and
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription product spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. In May 2017, the House of Representatives passed legislation to repeal and replace parts of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Thus, the full impact of the ACA, any law repealing and/or replacing elements of it, and the political uncertainty surrounding any repeal or replacement legislation on our business remains unclear.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal, and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop product candidates.

Additional regulation

In addition to the foregoing, state, and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act, and

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the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling, and disposal of various biologic, chemical, and radioactive substances used in, and wastes generated by, operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. Equivalent laws have been adopted in third countries that impose similar obligations.

Employees

As of June 30, 2017, we had 27 full-time employees, including 7 employees with Ph.D. or M.D. degrees. 19 of our employees are engaged in research and development activities and 8 are engaged in general and administrative activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Facilities

We occupy approximately 6,055 square feet of office space in Newton, MA under a lease that expires in May of 2018. In addition, we occupy approximately 5,133 square feet of laboratory space in Sudbury, MA under a lease that expires in February 2019. We have an option for an additional approximately 2,029 square feet of laboratory space at the Sudbury facility. We do not own any real property. We believe that this office and laboratory space is sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Legal Proceedings

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations or financial condition.

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MANAGEMENT

Executive Officers and Directors

Below is a list of the names, ages and positions of the individuals who serve as our executive officers, key persons and directors as of October 15, 2017.

Name	Age	Position
Executive Officers		
Alexey Margolin, Ph.D.	64	Chief Executive Officer and Director
Louis Brenner, M.D.	47	President and Chief Operating Officer
Edward Wholihan	57	Chief Financial Officer
Non-Employee Directors		
Axel Bolte(1)	45	Director
Stephen Kraus(1)	41	Director
Gino Santini(1)(2)	61	Director
Robert Tepper, M.D.(3)	62	Director
James N. Topper, M.D., Ph.D.(2)(3)	55	Director
Robert Alexander, Ph.D.(2)	48	Director

(1) Member of the Compensation Committee.
(2) Member of the Audit Committee.
(3) Member of the Nominating and Corporate Governance Committee.

Executive Officers

Alexey Margolin, Ph.D. is our co-founder and has served as our chief executive officer and director since September 2011. From September 2011 to February 2017, Dr. Margolin also served as our president. From September 2011 to April 2014 Dr. Margolin served as chief executive officer of Alcresta Therapeutics, Inc., or Alcresta, which he also co-founded and where he currently serves on the board of directors. From September 2011 to July 2013, Dr. Margolin also served as president of Alcresta. Prior to Alcresta, Dr. Margolin co-founded Alnara Pharmaceuticals, Inc., or Alnara, in 2008, where he was president and chief executive officer until 2010, when Alnara was acquired by Eli Lilly & Co., or Eli Lilly. Previously, Dr. Margolin also served as chief scientific officer of Altus Pharmaceuticals, Inc., or Altus, through 2007, where he initiated and led several therapeutics programs based on protein crystallization technology. In 2003, Dr. Margolin was elected fellow of the American Institute of Medicine and Biological Engineering. He is the author of more than 60 publications and is an inventor on several patents. Dr. Margolin holds both his M.S. in chemistry and Ph.D. in bio-organic chemistry from Moscow University. We believe that Dr. Margolin is qualified to serve on our board of directors because of his extensive experience and knowledge in the fields of protein drug development and enzymology.

Louis Brenner, M.D. has served as our chief operating officer since April 2015 and our president since February 2017. Dr. Brenner has more than a decade of industry leadership experience, including pharmaceutical development strategy, regulatory affairs, business development and marketing. From January 2014 to April 2015, Dr. Brenner served as senior vice president and chief medical officer at Idera Pharmaceuticals, Inc. (Nasdaq:IDRA). Dr. Brenner served as chief medical officer for Radius Health, Inc. (Nasdaq: RDUS), a biopharmaceutical company, from November 2011 to January 2014. Dr. Brenner has designed, planned and directed successful clinical trials at all stages and in multiple indications. He also serves on the board of directors of Goldfinch Biopharma Inc., a privately held biotechnology company. Dr. Brenner earned a B.S. from Yale University, an M.D. from Duke University and an M.B.A. from Harvard Business School. He completed his residency in internal medicine at Brigham and Women's Hospital and his fellowship in nephrology at Brigham and Women's Hospital and Massachusetts General Hospital. Dr. Brenner holds a clinical appointment at Brigham and Women's Hospital.

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Edward Wholihan has served as our chief financial officer since June 2016. Mr. Wholihan brings to us more than 25 years of financial, operational, and global business development leadership in the healthcare, life science, and technology sectors. From January 2015 to June 2016, Mr. Wholihan provided consulting and interim CFO and corporate development services to growth companies in the healthcare, life sciences, technology, and services industries. From June 2011 to July 2014, Mr. Wholihan served as chief financial officer of Medical Specialties Distributors LLC, or MSD, a healthcare services provider. Prior to MSD, he served as chief financial officer of Generation Health, Inc., a healthcare management company, from 2010 to 2011, and as chief financial officer and vice president of business development for Inovise Medical, Inc., a medical device company, from 2002 to 2009. Mr. Wholihan began his career at McKinsey & Company. Mr. Wholihan earned an M.B.A. from Stanford University's Graduate School of Business and a B.A. in economics from Yale University.

Non-Employee Directors

Axel Bolte has served as a member of our board of directors since October 2014. Since February 2017, Mr. Bolte has served as director, president and chief executive officer of Inozyme Pharma Inc., a private biotechnology company. Mr. Bolte also serves as an investment advisor to HBM Partners AG, a provider of investment advisory services in the life sciences, where he was employed in various capacities from March 2003 to January 2017. Mr. Bolte currently serves on the board of directors of Nabriva Therapeutics AG (Nasdaq: NBRV) and Ophthotech Corporation (Nasdaq: OPHT) and previously served on the board of directors of PTC Therapeutics, Inc. (Nasdaq: PTCT), all of which are publicly traded biotechnology companies. Mr. Bolte received a degree in biochemistry from the Swiss Federal Institute of Technology, Zurich, Switzerland and an M.B.A. from the University of St. Gallen, Switzerland. We believe that Mr. Bolte is qualified to serve on our board of directors because of his many years of service as one of our directors, his extensive experience as a venture capital investor in the life sciences industry and his service on the board of directors of other life sciences companies.

Stephen Kraus has served as a member of our board of directors since September 2011. Mr. Kraus has served as an investment professional at Bessemer Venture Partners, or BVP, a venture capital firm, since 2004 and has been a partner since 2011. He served on the board of directors of FlexPharma, Inc. (Nasdaq: FLKS) from April 2014 to January 2015, of Ovascience, Inc. (Nasdaq: OVAS) from July 2011 to December 2014 and of a number of privately-held life sciences companies. He previously served as a member of the board of directors of Verastem, Inc. (Nasdaq: VSTM) from November 2010 to November 2012, Sirtris Pharmaceuticals, Inc. (Nasdaq: SIRT) from 2005 to 2007 and Restore Medical, Inc. (Nasdaq: REST) from 2005 to 2008. He holds an M.B.A. from Harvard Business School and a B.A. from Yale University. We believe that Mr. Kraus is qualified to serve on our board of directors due to his experience in the life sciences industry as a venture capitalist and his service on the boards of directors of other life sciences companies.

Gino Santini has served as a member of our board of directors since February 2012. Mr. Santini is the Chairman of the board of directors of AMAG Pharmaceuticals (Nasdaq: AMAG), and a member of the board of directors of Horizon Pharma plc (Nasdaq: HZNP), Intercept Pharmaceuticals (Nasdaq: ICPT), Collegium Pharmaceuticals (Nasdaq: COLL), Intarcia Therapeutics, and Artax Biopharma. He previously served on the boards of SORIN SpA (SRN.MI) and Vitae Pharmaceuticals (Nasdaq: VTAE) until their acquisitions. Mr. Santini has been an advisor of European and US venture capital, pharmaceutical and biotechnology companies since 2011, when he retired after a 27-year career at Eli Lilly. Mr. Santini's last role at Eli Lilly was Senior Vice President of corporate strategy and business development. Mr. Santini holds a degree in Mechanical Engineering from the University of Bologna and an M.B.A. from the Simon School of Business, University of Rochester. We believe that Mr. Santini's long career at Eli Lilly and extensive domestic and international commercial, corporate strategy, business development and transaction experience are valuable skill sets for the board.

Robert Tepper, M.D. has served as a member of our board of directors since September 2011. Dr. Tepper is a partner of Third Rock Ventures, L.P., or Third Rock, which he co-founded in March 2007 and focuses on the

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formation, development and scientific strategy of Third Rock's portfolio companies, as well as actively identifying and evaluating new investments. Prior to joining Third Rock, Dr. Tepper served as president of research and development at Millennium Pharmaceuticals, Inc. Dr. Tepper serves as an adjunct faculty member at Harvard Medical School and Massachusetts General Hospital and is an advisory board member of several healthcare institutions, including the Partners HealthCare Center for Personalized Genetic Medicine, Harvard Medical School and Tufts Medical School. Dr. Tepper is a board member of the public companies Jounce Therapeutics, Inc. (Nasdaq: JNCE) and Kala Pharmaceuticals, Inc. (Nasdaq: KALA) and various private life sciences companies. Dr. Tepper was previously a board member of the public company bluebird bio, Inc. (Nasdaq: BLUE). Dr. Tepper also serves on the board of overseers at Tufts University and on the Council of the National Center for Advancing Translational Sciences at the National Institutes of Health. Dr. Tepper holds an A.B. in biochemistry from Princeton University and an M.D. from Harvard Medical School. We believe that Dr. Tepper's experience in the venture capital industry, particularly with biotech and pharmaceutical companies, combined with his experience building and operating research and development operations, on the boards of public and private life sciences companies and as faculty and advisory board member of several healthcare institutions, qualify him to serve as a member of our board of directors.

James N. Topper, M.D., Ph.D. has served as a member of our board of directors since September 2011. Since 2005, Dr. Topper has also served as the Managing General Partner at Frazier Healthcare Partners, a venture capital firm, with whom he served as a Partner from 2003 to 2005. Prior to that, from 2002 to 2003, Dr. Topper served as head of the Cardiovascular Research and Development Division at Millennium Pharmaceuticals, Inc., a biopharmaceutical company. Since June 2016, Dr. Topper has served as a member of the board of directors of Alpine lmmunosciences Inc., a biotechnology company (Nasdaq: ALPN), since May 2016, Dr. Topper has served as a member of the board of directors of Aptinyx Inc., a biopharmaceutical company, since March 2016, Dr. Topper has served as a member of the board of directors of Entasis Therapeutics Inc., a pharmaceutical company, and since July 2012 he has served on the board of Millendo Therapeutics, a pharmaceutical company. In addition, from April 2014 to March 2017, Dr. Topper served as a member of the board of directors of Sierra Oncology, Inc, (formerly ProNai Therapeutics, Inc.), an oncology company (Nasdaq: DNAI), since September 2011, Dr. Topper has served as a member of the board of directors of Alcresta Therapeutics, Inc., a specialty pharmaceutical company, and since 2007, Dr. Topper has served as a member of the board of directors of AnaptysBio, Inc., a biotechnology company (Nasdaq: ANAB). Dr. Topper is also a member of the board of directors of MavuPharma (since July 2016). From March 2011 to December 2013, Dr. Topper served as a member of the board of directors of Portola Pharmaceuticals, Inc., a biopharmaceutical company (Nasdaq: PTLA), and from 2004 to April 2015 as a member of the board of directors of Amicus Therapeutics, Inc., a biopharmaceutical company (Nasdaq: FOLD). Dr. Topper received a B.S. in biology from the University of Michigan and an M.D. and a Ph.D. in biophysics from Stanford University. We believe that Dr. Topper's experience overseeing Frazier Healthcare investments in biotechnology, senior-management experience in our industry, significant knowledge of medical and scientific matters affecting our business, and understanding of our industry provide him with the qualifications and skills to serve on our board of directors.

Robert Alexander, Ph.D. has served as a member of our board of directors since June 2016. Since April 2017, Dr. Alexander has served as the chief executive officer of Allakos Inc. From March 2013 to March 2017, Dr. Alexander served as the chief executive officer of ZS Pharma, Inc., or ZS Pharma. He also served on the Board of Directors of ZS Pharma from March 2013 to December 2015, when it was acquired by AstraZeneca PLC, including as chairman of the Board of Directors from March 2013 to March 2014. From November 2005 to March 2013, Dr. Alexander served as a director at Alta Partners, a venture capital firm in life sciences. In addition, he acted as executive chairman and interim chief executive officer of SARcode Biosciences Inc. (acquired by Shire plc in April 2013), a biopharmaceutical company. Dr. Alexander completed his post-doctoral fellowship at Stanford University in the pathology department. He also holds a Ph.D. in immunology from the University of North Carolina and a B.A. in zoology from Miami University of Ohio. We believe Dr. Alexander is qualified to serve on our board of directors based on his background and experience in the life sciences sector.

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Board Composition and Election of Directors

Board Composition

Our board of directors currently consists of seven members, all of whom were elected pursuant to the board composition provisions of our stockholders voting agreement, which is described under "Certain Relationships and Related Party Transactions—Stockholders Voting Agreement" in this prospectus. The board composition provisions in our voting agreement will terminate immediately prior to the consummation of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and governance committee and board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity and is not limited to race, gender or national origin. We have no formal policy regarding board diversity. Our nominating and governance committee's and board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape and professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

Our restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Director Independence

Our common stock is listed on The Nasdaq Stock Market, or Nasdaq. Applicable Nasdaq rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq rules require that, (i) on the date of the completion of the offering, at least one member of each of a listed company's audit, compensation and nominating and corporate governance committees be independent, (ii) within 90 days of the date of the completion of the offering, a majority of the members of such committees be independent and (iii) within one year of the date of the completion of the offering, all the members of such committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries.

In September 2017, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that all directors other than Dr. Margolin are "independent directors" as defined under applicable Nasdaq rules. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director.

There are no family relationships among any of our directors or executive officers.

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Staggered Board

In accordance with the terms of our restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering, our board of directors will be divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms. Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

- Our Class I directors will be, Alexey Margolin, Ph.D., Stephen Kraus and James N. Topper, M.D., Ph,D.;
- Our Class II directors will be Axel Bolte and Robert Tepper, M.D.; and
- Our Class III directors will be Robert Alexander, Ph.D. and Gino Santini.

Our restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class shall consist of one third of the board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Board Committees

Our board of directors has three standing committees: the audit committee, the compensation committee and the nominating and corporate governance committee. Our board of directors may establish other committees from time to time. Each of these committees operates under a charter that has been approved by our board of directors. The composition of all of our committees complies with all applicable requirements of the Sarbanes-Oxley Act of 2002, Nasdaq and Securities and Exchange Commission, or SEC, rules and regulations.

Audit Committee

Our audit committee consists of Robert Alexander, Ph.D., Gino Santini and James N. Topper, M.D., Ph.D., with Dr. Alexander serving as chairman of the committee. Our board of directors has determined that each of the directors serving on our audit committee meets the independence requirements of Rule 10A-3 under the Exchange Act and the applicable listing standards of Nasdaq. Our board of directors has determined that Dr. Alexander is an “audit committee financial expert” within the meaning of the SEC regulations and applicable listing standards of Nasdaq. In making this determination, our board has considered the formal education and nature and scope of his previous experience, coupled with past and present service on various audit committees. Our audit committee assists our board of directors in its oversight of our accounting and financial reporting process and the audits of our financial statements. The audit committee’s responsibilities include:

- appointing, approving the compensation of, reviewing the performance of, and assessing the independence of our independent registered public accounting firm;
- pre-approving audit and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the internal audit plan with the independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- reviewing the adequacy of our internal control over financial reporting;

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- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending, based upon its review and discussions with management and the independent registered public accounting firm, whether our audited consolidated financial statements shall be included in our Annual Report on Form 10-K;
- preparing the audit committee report required by the rules of the SEC to be included in our annual proxy statement; and
- reviewing all related party transactions for potential conflict of interest situations and approving all such transactions.

All audit services to be provided to us and all non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Compensation Committee

Our compensation committee consists of Axel Bolte, Stephen Kraus and Gino Santini, with Mr. Santini serving as chairman of the committee. Our board of directors has determined that each member of the compensation committee is "independent" as defined under the applicable listing standards of Nasdaq. Our compensation committee assists our board of directors in the discharge of its responsibilities relating to the compensation of our executive officers. The compensation committee's responsibilities include:

- annually reviewing and recommending for approval by the independent directors of the board individual and corporate goals and objectives relevant to the compensation of our executive officers;
- evaluating the performance of our executive officers in light of such individual and corporate goals and objectives and determining the compensation of our executive officers;
- appointing, compensating and overseeing the work of any compensation consultant, legal counsel or other advisor retained by the compensation committee;
- conducting the independence assessment outlined in Nasdaq rules with respect to any compensation consultant, legal counsel or other advisor retained by the compensation committee;
- annually reviewing and reassessing the adequacy of the committee charter in its compliance with the listing requirements of Nasdaq;
- overseeing and administering our compensation and similar plans;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and making recommendations to the board of directors with respect to director compensation;
- reviewing and approving stock option grants, and making recommendations to the board of directors with respect to stock option grants made to directors, executive officers, senior vice presidents or anyone reporting directly to our chief executive officer; and
- reviewing and discussing with management the compensation discussion and analysis, if any, to be included in our annual proxy statement.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Robert Tepper, M.D. and James N. Topper, M.D., Ph.D., with Dr. Tepper serving as chairman of the committee. Our board of directors has determined that each member of the nominating and corporate governance committee is "independent" as

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defined under the applicable listing standards of NASDAQ. The nominating and corporate governance committee's responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- developing and recommending to the board of directors a set of corporate governance principles;
- reviewing and discussing with the board of directors corporate succession plans for the chief executive officer and other senior management positions;
- reviewing policies related to risk assessment and risk management; and
- establishing, maintaining and overseeing our Code of Business Conduct and Ethics.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or compensation committee. None of the members of our compensation committee has ever been employed by us. For a description of transactions between us and members of our compensation committee and affiliates of such members, please see the section of this prospectus titled "Certain Relationships and Related Party Transactions."

Code of Business Conduct and Ethics

We have adopted, effective upon the effectiveness of the registration statement of which this prospectus forms a part, a written code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Upon the closing of this offering, our code of business conduct and ethics will be posted on the Corporate Governance section of our website, which is located at www.allenapharma.com. We intend to disclose amendments to the code, or any waivers of its requirements, on our website or in a current report on Form 8-K as may be required by SEC or Nasdaq rules.

Board Leadership Structure and Board's Role in Risk Oversight

The positions of our chairman of the board and chief executive officer are separated. Separating these positions allows our chief executive officer to focus on our day-to-day business, while allowing the chairman of the board to lead the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that the chief executive officer must devote to his position in the current business environment, as well as the commitment required to serve as our chairman, particularly as the board of directors' oversight responsibilities continue to grow. Our board of directors also believes that this structure ensures a greater role for the independent directors in the oversight of our company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our board of directors. This leadership structure is also preferred by a significant number of our stockholders. Our board of directors believes its administration of its risk oversight function has not affected its leadership structure.

Although our bylaws that will be in effect upon the completion of this offering will not require our chairman and chief executive officer positions to be separate, our board of directors believes that having separate positions

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is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including those described under the section titled "Risk Factors." Our board of directors is actively involved in oversight of risks that could affect us. This oversight is conducted primarily by our full board of directors, which has responsibility for general oversight of risks.

Following the completion of this offering, our board of directors will satisfy this responsibility through full reports by each committee chair regarding the committee's considerations and actions, as well as through regular reports directly from officers responsible for oversight of particular risks within our company. Our board of directors believes that full and open communication between management and the board of directors is essential for effective risk management and oversight.

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EXECUTIVE COMPENSATION

Overview

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to "smaller reporting companies," as such term is defined in the rules promulgated under the Securities Act of 1933, as amended.

This section provides an overview of the compensation awarded to, earned by, or paid to our principal executive officer and our next two most highly compensated executive officers in respect of their service to us for our fiscal year ended December 31, 2016. We refer to these individuals as our named executive officers. Our named executive officers are:

- Alexey Margolin, Ph.D., our Chief Executive Officer;
- Louis Brenner, M.D., our President and Chief Operating Officer; and
- Edward Wholihan, our Chief Financial Officer.

Our executive compensation program is based on a pay for performance philosophy. Compensation for our executive officers is composed primarily of the following main components: base salary, bonus and long term equity incentives. Our executive officers, like all full-time employees, are eligible to participate in our health and welfare benefit plans.

2016 Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by or paid to each of our named executive officers during the year ended December 31, 2016.

Name and Principal Position	Year	Salary ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(2)	All Other Compensation ($)	Total ($)
Alexey Margolin, Ph.D.						
Chief Executive Officer	2016	447,927	147,982	179,171	1,478	776,558
Louis Brenner, M.D.						
President and Chief Operating Officer	2016	370,656	85,764	129,730	2,157	588,307
Edward Wholihan						
Chief Financial Officer	2016	161,538	208,659	55,650	798	426,645

(1) Amounts reflect the grant date fair value of option awards granted or modified in 2016 in accordance with the Financial Accounting Standards Board Accounting Standards Codification Topic 718, or ASC 718. Such grant date fair value does not take into account any estimated forfeitures related to service-vesting conditions. For information regarding assumptions underlying the valuation of equity awards, see Note 2 to our financial statements and the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates—Stock-based Compensation" included elsewhere in this prospectus. These amounts do not correspond to the actual value that may be recognized by the named executive officers upon vesting of applicable awards.

(2) The amounts reported represent bonuses based upon the achievement of company and individual performance objectives for the year ended December 31, 2016.

Narrative to Summary Compensation Table

Base Salary

We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. None of our named executive officers is currently party to an

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employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary.

Annual Bonus

We have an annual objective-setting and review process for our named executive officers that is the basis for determination of potential annual bonuses. Our board of directors reviews and approves both the annual objectives and the payment of annual bonuses for our executives. Our employment agreements with our named executive officers provide that they will be eligible for annual performance-based bonuses up to a specific percentage of their salary, subject to approval by our board of directors. The performance-based bonus is tied to a set of specified corporate goals for our named executive officers and we conduct an annual performance review to determine the attainment of such goals. Our management may propose bonus awards to our board of directors primarily based on such review process. Our board of directors makes the final determination of both the specified corporate goals and the eligibility requirements for and the amount of such bonus awards.

Equity Compensation

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our named executive officers and from time to time may grant equity incentive awards to them in the form of stock options.

We typically grant stock option awards at the start of employment to each executive and our other employees. To date, we have not maintained a practice of granting additional equity on an annual basis, but we have retained discretion to provide additional targeted grants in certain circumstances.

We award our stock options on the date our board of directors approves the grant. We set the option exercise price and grant date fair value based on our per-share estimated valuation on the date of grant. For grants in connection with initial employment, vesting begins on the initial date of employment. Time vested stock option grants to our executives and other employees typically vest 25% on the first anniversary of grant or, if earlier, the initial employment date and in equal monthly installments thereafter, through the fourth anniversary of the vesting commencement date, and have a term of ten years from the grant date.

Employment Agreements with Our Named Executive Officers and Our Chief Executive Officer

We entered into employment agreements with each of Dr. Margolin, Dr. Brenner and Mr. Wholihan on June 19, 2014, March 17, 2015 and June 20, 2016, respectively. These agreements set forth the initial terms and conditions of each executive's employment with us, including base salary, target annual bonus opportunity and standard employee benefit plan participation. In connection with the offering, we entered into an employment agreement with each of our named executive officers. Except as noted below, these employment agreements provide for "at will" employment. The material terms of these employment agreements with our named executive officers are described below. The terms "cause," "good reason" and "change in control" referred to below are defined in each named executive officer's employment agreement.

Dr. Margolin

Pursuant to Dr. Margolin's employment agreement dated October 23, 2017, Dr. Margolin's initial base salary shall be equal to $513,200, his initial annual target incentive compensation shall be equal to 50 percent of his base salary, and he shall be eligible to participate in the Company's benefit plan as in effect from time to time. In addition, in the event that his employment is terminated by us without "cause" (as defined in his

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employment agreement) or he terminates his employment for "good reason" (as defined in his employment agreement), and subject to the delivery of a fully effective release of claims, he will be entitled to an amount equal to 12 months of his then-current base salary plus 12 months of his target annual incentive compensation for the prior fiscal year, payable in substantially equal installments for a period of 12 months following his termination of employment, plus our continued payment of the employer portion of health insurance premiums for 12 months or, if earlier, until such time as Dr. Margolin's COBRA period expires or he becomes eligible for group health insurance from another employer. In addition, all time-based stock options or other time-based stock awards granted to Dr. Margolin prior to the effectiveness of his employment agreement will accelerate and vest in full.

If Dr. Margolin's employment is terminated by us without cause or he terminates his employment for good reason, in each case within 12 months after a change in control, then in lieu of the foregoing severance, and subject to the delivery of a fully effective release of claims, Dr. Margolin will be entitled to receive (i) a lump sum amount equal to the sum of 18 months of his then-current base salary plus his target annual incentive compensation for the year in which the termination occurs, (ii) a prorated portion of the target annual incentive compensation for the year in which the date of termination occurs, payable when the annual incentive compensation would otherwise be paid, (iii) any earned, but unpaid annual bonus for the year immediately prior to the year in which the date of termination occurs and (iv) continued payment of the employer portion of health insurance premiums for 18 months or, if earlier, until such time as Dr. Margolin's COBRA period expires or he becomes eligible for group health insurance from another employer. In addition, all time-based stock options or other time-based stock awards granted to Dr. Margolin will accelerate and vest in full.

Dr. Brenner

Pursuant to Dr. Brenner's employment agreement dated October 18, 2017, Dr. Brenner's initial base salary shall be equal to $396,400, his initial annual target incentive compensation shall be equal to 40 percent of his base salary, and he shall be eligible to participate in the Company's benefit plan as in effect from time to time. In addition, in the event that his employment is terminated by us without "cause" (as defined in his employment agreement) or he terminates his employment for "good reason" (as defined in his employment agreement), and subject to delivery of a fully effective release of claims he will be entitled to an amount equal to nine months of his then-current base salary plus nine months of his target annual incentive compensation for the prior fiscal year, payable in substantially equal installments for a period of nine months following his termination of employment, plus our continued payment of the employer portion of health insurance premiums for nine months or, if earlier, until such time as Dr. Brenner's COBRA period expires or he becomes eligible for group health insurance from another employer.

If Dr. Brenner's employment is terminated by us without cause or he terminates his employment for good reason, in each case within 12 months after a change in control, then in lieu of the foregoing severance, and subject to the delivery of a fully effective release of claims, Dr. Brenner will be entitled to receive (i) a lump sum amount equal to the sum of 12 months of his then-current base salary plus his target annual incentive compensation for the year in which the termination occurs, (ii) a prorated portion of the target annual incentive compensation for the year in which the date of termination occurs, payable when the annual incentive compensation would otherwise be paid, (iii) any earned, but unpaid annual bonus for the year immediately prior to the year in which the date of termination occurs and (iv) continued payment of the employer portion of health insurance premiums for 12 months or, if earlier, until such time as Dr. Brenner's COBRA period expires or he becomes eligible for group health insurance from another employer. In addition, all time-based stock options or other time-based stock awards granted to Dr. Brenner will accelerate and vest in full.

Mr. Wholihan

Pursuant to Mr. Wholihan's employment agreement dated October 17, 2017, Mr. Wholihan's initial base salary shall be equal to $350,600, his initial annual target incentive compensation shall be equal to 35 percent of

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his base salary, and he shall be eligible to participate in the Company's benefit plan as in effect from time to time. In addition, in the event that his employment is terminated by us without "cause" (as defined in his employment agreement) or he terminates his employment for "good reason" (as defined in his employment agreement), and subject to delivery of a fully effective release of claims he will be entitled to an amount equal to nine months of his then-current base salary plus nine months of his target annual incentive compensation for the prior fiscal year, payable in substantially equal installments for a period of nine months following his termination of employment, plus our continued payment of the employer portion of health insurance premiums for nine months or, if earlier, until such time as Mr. Wholihan's COBRA period expires or he becomes eligible for group health insurance from another employer.

If Mr. Wholihan's employment is terminated by us without cause or he terminates his employment for good reason, in each case within 12 months after a change in control, then in lieu of the foregoing severance, and subject to the delivery of a fully effective release of claims, Mr. Wholihan will be entitled to receive (i) a lump sum amount equal to the sum of 12 months of his then-current base salary plus his target annual incentive compensation for the year in which the termination occurs, (ii) a prorated portion of the target annual incentive compensation for the year in which the date of termination occurs, payable when the annual incentive compensation would otherwise be paid, (iii) any earned, but unpaid annual bonus for the year immediately prior to the year in which the date of termination occurs and (iv) continued payment of the employer portion of health insurance premiums for 12 months or, if earlier, until such time as Mr. Wholihan's COBRA period expires or he becomes eligible for group health insurance from another employer. In addition, all time-based stock options or other time-based stock awards granted to Mr. Wholihan will accelerate and vest in full.

Other Agreements

We have also entered into employee confidentiality, inventions, non-solicitation and non-competition agreements with each of our named executive officers. Under such agreements, each named executive officer has agreed (1) not to compete with us during his or her employment and for a period of one year (nine months, in Mr. Brenner's case) after the termination of such employment, (2) not to solicit our employees during his or her employment and for a period of one year (nine months, in Mr. Brenner's case) after the termination of such employment, (3) to protect our confidential and proprietary information and (4) to assign to us related intellectual property developed during the course of his or her employment.

2016 Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning outstanding equity awards for each of our named executive officers as of December 31, 2016. All equity awards granted to our named executive officers were made pursuant to our 2011 Stock Incentive Plan, as amended, or the 2011 Plan.

	Option Awards(1)				
Name	Vesting Start Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Alexey Margolin, Ph.D.	3/5/2014	8,814	12,020	0.75	3/4/2024
	5/15/2014	3,928	6,070	0.75	5/14/2024
	12/16/2014	107,810	107,810	1.17	12/15/2024
	12/8/2015	32,942	98,826	1.59	3/9/2026
Louis Brenner, M.D.	4/6/2015	84,682	118,555	1.17	6/17/2025
	12/8/2015	19,166	57,499	1.59	3/9/2026
Edward Wholihan	6/20/2016	—	192,031	1.59	9/14/2026

(1) Each stock option vests over four years, with 25% of the shares vesting on the first anniversary of the vesting start date, and the remaining shares vesting in 36 equal monthly installments thereafter.

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2016 Director Compensation

Except as set forth below, in the year ended December 31, 2016, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors for their service as a director in 2016. Dr. Margolin, our chief executive officer and a member of our board of directors, did not receive any compensation for his service as a member of our board of directors during 2016. Dr. Margolin's compensation for service as an employee for fiscal year 2016 is presented above in the "2016 Summary Compensation Table."

Name	Fees Earned or Paid in Cash ($)	Option Awards ($) (1)	All Other Compensation ($)	Total ($)
Axel Bolte	—	—	—	—
Stephen Kraus	—	—	—	—
Gino Santini	40,000(2)	16,164(3)	—	56,164
Robert Tepper, M.D.	—	—	—	—
James Topper, M.D., Ph.D.	—	—	—	—
Robert Alexander, Ph.D.	20,000(4)	48,758(5)	—	68,758

(1) Amounts reflect the grant date fair value of option awards granted in 2014 in accordance with ASC 718. Such grant-date fair value does not take into account any estimated forfeitures related to service-vesting conditions. For information regarding assumptions underlying the valuation of equity awards, see Note 2 to our consolidated financial statements and the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates—Stock-Based Compensation" included elsewhere in this prospectus. These amounts do not correspond to the actual value that may be recognized by the directors upon vesting.

(2) Pursuant to a letter agreement with us, Mr. Santini is entitled to receive an annual cash retainer of $40,000, paid quarterly in arrears, for his service on the board of directors.

(3) Represents an option to purchase 14,374 shares of our common stock granted on March 10, 2016, which vested as to 25% of the shares on December 8, 2016 and vest to an additional 2.083% of the total shares on the same day of each successive month thereafter until December 8, 2019. As of December 31, 2016, Mr. Santini held 28,748 unexercised options.

(4) Pursuant to a letter agreement with us, Dr. Alexander is entitled to receive an annual cash retainer of $40,000, paid quarterly in arrears, for his service on the board of directors. Dr. Alexander joined the board of directors in June 2016 and the amount above reflects the portion of his annual retainer earned for his partial year of service.

(5) Represents an option to purchase 43,603 shares of our common stock granted on June 9, 2016, which vests as to 25% of the shares on June 9, 2017 and vest to an additional 2.083% of the total shares on the same day of each successive month thereafter until June 9, 2020. As of December 31, 2016, Dr. Alexander held 43,603 unexercised options.

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Non-Employee Director Compensation Policy

Our board of directors has adopted a non-employee director compensation policy, effective as of the completion of this offering, that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee will be paid cash compensation from and after the completion of this offering, as set forth below:

	Annual Retainer
Board of Directors:	
All non-employee members	$40,000
Audit Committee:	
Members	$ 7,500
Chair	$15,000
Compensation Committee:	
Members	$ 6,000
Chair	$12,000
Nominating and Corporate Governance Committee:	
Members	$ 4,000
Chair	$ 8,000

In addition, each non-employee director will be granted a non-qualified stock option to purchase 20,364 shares of common stock on the date of such director's election or appointment to the board of directors, which will vest in equal annual installments over the three years following the grant date, subject to continued service as a director; provided that, if not already vested, such stock option will vest and become fully exercisable on the date of the third annual meeting of stockholders following the grant date. On the date of each annual meeting of stockholders of our company, each continuing non-employee director who has served as a director for the previous six months will be granted a non-qualified stock option to purchase 10,182 shares of common stock, which will vest and become fully exercisable upon the earlier to occur of the first anniversary of the grant date or the date of the next annual meeting of stockholders following the date of grant, subject to continued service as a director through such date.

Compensation Risk Assessment

We believe that, although a portion of the compensation provided to our executive officers and other employees is performance-based, our executive compensation program does not encourage excessive or unnecessary risk taking. This is primarily due to the fact that our compensation programs are designed to encourage our executive officers and other employees to remain focused on both short-term and long-term strategic goals, in particular in connection with our pay-for-performance compensation philosophy. As a result, we do not believe that our compensation programs are reasonably likely to have a material adverse effect on us.

Employee Equity Plans

The equity incentive plans described in this section are our 2011 Plan, the Allena Pharmaceuticals, Inc. 2017 Stock Option and Incentive Plan, or the 2017 Plan, and the 2017 Employee Stock Purchase Plan, or the ESPP. Prior to this offering, we granted awards to eligible participants under the 2011 Plan. Following the closing of this offering, we expect to grant awards to eligible participants only under the 2017 Plan.

2011 Stock Incentive Plan

Our 2011 Plan was approved by our board of directors and stockholders on September 8, 2011. The 2011 Plan was most recently amended in November 2015 with the approval of both our board of directors and our

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stockholders. Under the 2011 Plan, we have reserved for issuance an aggregate of 2,293,272 shares of our common stock. The number of shares of common stock reserved for issuance is subject to adjustment in the event of a stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in our capitalization.

The shares of common stock underlying awards that expire or are terminated, surrendered or canceled without having been fully exercised or are forfeited or repurchased or result in shares of common stock not being issued under the 2011 Plan are added back to the shares of common stock available for issuance under the 2011 Plan. In addition, shares of common stock tendered to us by a participant to exercise an award are added back to the shares available for grant under the 2011 Plan.

Our board of directors has acted as administrator of the 2011 Plan. The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, and to determine the specific terms and conditions of each award, subject to the provisions of the 2011 Plan. Persons eligible to participate in the 2011 Plan are those employees, officers and directors of, and consultants and advisors to, the company as selected from time to time by the administrator in its discretion.

The 2011 Plan permits the granting of (1) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, or the Code, and (2) options that do not so qualify. The per share option exercise price of each option will be determined by the administrator but may not be less than 100% of the fair market value of the common stock on the date of grant. The term of each option will be fixed by the administrator. The administrator will determine at what time or times each option may be exercised. In addition, the 2011 Plan permits the granting of restricted shares of common stock, restricted stock units and other stock-based awards.

The 2011 Plan provides that upon the occurrence of a "reorganization event," as defined in the 2011 Plan, our board of directors may take one or more of the following actions as to some or all awards (other than restricted stock) outstanding under the 2011 Plan: (1) provide that outstanding awards will be assumed or substituted by the acquiring or successor corporation, (2) upon written notice to holders of outstanding awards, provide that unexercised awards will terminate immediately prior to the consummation of the reorganization event unless exercised by the participant (to the extent exercisable) within a specified period following the date of such notice, (3) provide that all awards will become exercisable, realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon the reorganization event, (4) in the event of a reorganization event in which the holders of common stock will receive a cash payment for each share surrendered, make or provide for a per share cash payment to holders of awards in an amount equal to the difference between the per share cash consideration in the reorganization event and the per share exercise price of the outstanding award, (5) provide that, in connection with a liquidation or dissolution of the company, awards will convert into the right to receive liquidation proceeds or (6) any combination of the foregoing.

Upon the occurrence of a reorganization event other than a liquidation or dissolution of our company, our repurchase and other rights under each restricted stock award will inure to the benefit of our successor, and will apply to the cash, securities or other property which the common stock was converted into or exchanged for pursuant to the reorganization event. Upon the occurrence of a reorganization event involving the liquidation or dissolution of our company, except to the extent provided to the contrary in the instrument evidencing the restricted stock award or any other agreement between the holder of restricted stock and us, all restrictions and conditions on outstanding restricted stock awards will automatically be deemed terminated or satisfied.

The administrator may amend, suspend or terminate the 2011 Plan at any time, subject to stockholder approval where such approval is required by applicable law. The administrator of the 2011 Plan may also amend, modify or terminate any outstanding award, provided that no amendment to an award may materially and adversely affect a participant's rights without his or her consent.

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The 2011 Plan will terminate automatically upon the earlier of 10 years from the date on which the 2011 Plan was adopted by our board of directors or the date the Plan was approved by our stockholders. As of June 30, 2017, options to purchase 1,394,299 shares of common stock were outstanding under the 2011 Plan. Our board of directors has determined not to make any further awards under the 2011 Plan following the closing of this offering.

2017 Stock Option and Incentive Plan

Our 2017 Plan was adopted by our board of directors on October 16, 2017 and approved by our stockholders on October 16, 2017 and became effective upon the effectiveness of the registration statement of which this prospectus forms a part. The 2017 Plan replaced the 2011 Plan as our board of directors has determined not to make additional awards under the 2011 Plan following the effectiveness of the 2017 Plan. The 2017 Plan allows the compensation committee to make equity-based and cash-based incentive awards to our officers, employees, directors and other key persons (including consultants).

We have initially reserved 2,038,021 shares of our common stock for the issuance of awards under the 2017 Plan, which include the shares of common stock remaining available for issuance under the 2011 Plan immediately prior to the effectiveness of the 2017 Plan, collectively, the Initial Limit. The 2017 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2018, by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation committee, or the Annual Increase. The number of shares reserved under the 2017 Plan is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares we issue under the 2017 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2017 Plan and the 2011 Plan will be added back to the shares of common stock available for issuance under the 2017 Plan.

Stock options and stock appreciation rights with respect to no more than 1,222,217 shares of common stock may be granted to any one individual in any one calendar year. The maximum number of shares that may be issued as incentive stock options may not exceed the Initial Limit cumulatively increased on January 1, 2018 and on each January 1 thereafter by the lesser of the Annual Increase or 2,038,021 shares. The value of all awards made under the 2017 Plan and all other cash compensation paid by us to any non-employee director in any calendar year will not exceed $1,000,000.

The 2017 Plan is administered by our compensation committee. Our compensation committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2017 Plan. Persons eligible to participate in the 2017 Plan are those full or part-time officers, employees, non-employee directors and other key persons (including consultants) as selected from time to time by our compensation committee in its discretion.

The 2017 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each option will be fixed by our compensation committee and may not exceed 10 years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock equal to

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the value of the appreciation in our stock price over the exercise price. The exercise price may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed 10 years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Our compensation committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. Our compensation committee may also grant shares of common stock that are free from any restrictions under the 2017 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee may grant performance share awards to participants that entitle the recipient to receive awards of common stock upon the achievement of certain performance goals and such other conditions as our compensation committee shall determine. Our compensation committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock.

Our compensation committee may grant cash bonuses under the 2017 Plan to participants, subject to the achievement of certain performance goals.

Our compensation committee may grant awards of restricted stock, restricted stock units, performance share awards or cash-based awards under the 2017 Plan that are intended to qualify as "performance-based compensation" under Section 162(m) of the Code. Such awards will only vest or become payable upon the attainment of performance goals that are established by our compensation committee and related to one or more performance criteria. The performance criteria that could be used with respect to any such awards include: cash flow (including, but not limited to, operating cash flow and free cash flow); sales or revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of our common stock; economic value-added; development, clinical, regulatory or commercial milestones; acquisitions or strategic transactions, partnerships or joint ventures; operating income (loss); return on capital, assets, equity, or investment; stockholder returns; return on sales; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of our common stock; sales or market shares; number of customers; operating income and/or other strategic, financial or operational objectives, any of which may be measured either in absolute terms or as compared to any incremental increase or as compared to results of a peer group. From and after the time that we become subject to Section 162(m) of the Code, the maximum award that is intended to qualify as "performance-based compensation" under Section 162(m) of the Code that may be made to certain of our officers during any one calendar year period is 488,887 shares of common stock with respect to a share-based award and $5,000,000 with respect to a cash-based award.

The 2017 Plan provides that upon the effectiveness of a "sale event," as defined in the 2017 Plan, an acquirer or successor entity may assume, continue or substitute for the outstanding awards under the 2017 Plan. To the extent that awards granted under the 2017 Plan are not assumed or continued or substituted by the successor entity, upon the effective time of the sale event, all outstanding awards granted under the 2017 Plan will terminate. In such a case, all options and stock appreciation rights that are not exercisable immediately prior to the effective time of the sale event will become fully exercisable as of the effective time of the sale event, all other awards with time-based vesting, conditions or restrictions, will become fully vested and nonforfeitable as of the effective time of the sale event and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in the discretion of our compensation committee. In the event of such termination, individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) prior to the sale event. In addition,

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in connection with the termination of outstanding awards upon a sale event, we may make or provide for a cash payment to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share cash consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights.

Our board of directors may amend or discontinue the 2017 Plan and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2017 Plan require the approval of our stockholders.

No awards may be granted under the 2017 Plan after the date that is 10 years from the effective date of the 2017 Plan. No awards under the 2017 Plan have been made prior to the date hereof.

Employee Stock Purchase Plan

On October 16, 2017, our board of directors adopted the ESPP and on October 16, 2017, our stockholders approved the ESPP. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. The ESPP initially reserves and authorizes the issuance of up to a total of 206,284 shares of common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2018, by the lesser of (i) 412,568 shares of common stock, (ii) 1% of the outstanding number of shares of our common stock on the immediately preceding December 31 or (iii) such lesser number of shares as determined by the ESPP administrator. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

All employees whose customary employment is for more than 20 hours per week are eligible to participate in the ESPP. However, any participating employee who would own 5% or more of the total combined voting power or value of all classes of stock after an option were granted under the ESPP would not be eligible to purchase shares under the ESPP.

We will make one or more offerings each year to our employees to purchase shares under the ESPP. Offerings will usually begin on each January 1 and July 1 and will continue for six-month periods, referred to as offering periods. Each eligible employee may elect to participate in any offering by submitting an enrollment form at least 15 business days before the relevant offering date.

Each employee who is a participant in the ESPP may purchase shares by authorizing payroll deductions of up to 10% of his or her base compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares on the last business day of the offering period at a price equal to 85% of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower. Under applicable tax rules, an employee may purchase no more than $25,000 worth of shares of common stock, valued at the start of the purchase period, under the ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

The ESPP may be terminated or amended by our board of directors at any time. An amendment that increases the number of shares of common stock authorized under the ESPP and certain other amendments require the approval of our stockholders.

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Senior Executive Cash Incentive Bonus Plan

In September 2017, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan. The Bonus Plan provides for cash bonus payments based upon the attainment of performance targets established by our compensation committee. The payment targets will be related to financial and operational measures or objectives with respect to our company, or Corporate Performance Goals, as well as individual performance objectives.

Our compensation committee may select Corporate Performance Goals from among the following: cash flow (including, but not limited to, operating cash flow and free cash flow); sales or revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of our common stock; economic value-added; development, clinical, regulatory or commercial milestones; acquisitions or strategic transactions, partnerships or joint ventures; operating income (loss); return on capital, assets, equity, or investment; stockholder returns; return on sales; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of our common stock; sales or market shares; number of customers; operating income and/or other strategic, financial or operational objectives, any of which may be measured in absolute terms, as compared to any incremental increase, in terms of growth, as compared to results of a peer group, against the market as a whole, compared to applicable market indices and/or measured on a pre-tax or post-tax basis.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The Corporate Performance Goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the Corporate Performance Goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period. The Bonus Plan also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion.

401(k) Plan

We maintain the Allena Pharmaceuticals, Inc. 401(k) Plan, a tax-qualified retirement plan for our employees. Our 401(k) plan is intended to qualify under Section 401(k) of the Code so that contributions to our 401(k) plan by employees or by us, and the investment earnings thereon, are not taxable to the employees until withdrawn from our 401(k) plan, and so that contributions by us, if any, will be deductible by us when made. Under our 401(k) plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit and to have the amount of such reduction contributed to our 401(k) plan.

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CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than compensation arrangements, during our last three fiscal years, we have engaged in the following transactions with our directors and executive officers and holders of more than 5% of our voting securities and affiliates of our directors, executive officers and such 5% stockholders, in which the amount involved exceeds $120,000. We believe that all of the transactions described below were made on terms no less favorable to us than could have been obtained from unaffiliated third parties.

Sales and Purchases of Securities

Series B Financing

On November 6, 2014, we issued and sold to investors an aggregate of 19,841,270 shares of our Series B preferred stock, at a price per share of $1.26, for aggregate cash consideration of $25,000,000, pursuant to a stock purchase agreement entered into with investors on October 29, 2014.

The following table summarizes the participation in the closing of the Series B preferred stock financing by any of our directors, executive officers, holders of more than 5% of our voting securities, or any member of the immediate family of the foregoing persons.

Name	Shares of Series B Preferred Stock
Frazier Healthcare Partners VI, L.P.(1)	4,629,630
Third Rock Ventures II, L.P.(2)	4,629,630
Affiliates of Bessemer Venture Partners(3)	3,174,603
HBM BioCapital II LP(4)	5,952,380

(1) Frazier Healthcare Partners VI, L.P. is a holder of more than 5% of our voting securities. James N. Topper, M.D., Ph.D. is a managing general partner of Frazier Healthcare Partners, of which Frazier Healthcare Partners VI, L.P. is an affiliated fund, and is a member of our board of directors.

(2) Third Rock Ventures II, L.P. is a holder of more than 5% of our voting securities. Robert Tepper is a manager of TRV GP II, LLC, of which Third Rock Ventures II, L.P. is an affiliated fund, and is a member of our board of directors.

(3) Includes 1,015,873 shares of our Series B preferred stock to Bessemer Venture Partners VII L.P., 444,444 shares of our Series B preferred stock to Bessemer Venture Partners VII Institutional L.P. and 1,714,286 shares of our Series B preferred stock to BVP VII Special Opportunity Fund L.P., or, collectively, the BVP Entities. The BVP Entities collectively hold more than 5% of our voting securities. The General Partner of the BVP Entities is Deer VII & Co. L.P., or Deer L.P. The General Partner of Deer L.P. is Deer VII & Co. Ltd., or Deer Ltd. Each of Deer L.P. and Deer Ltd. may be deemed to have voting and dispositive power of the shares held by the BVP Entities. Robert Goodman, David Cowan, J. Edmund Colloton, Jeremy S. Levine, Robert M. Stavis and Byron Deeter are the directors of Deer Ltd. Investment and voting decisions with respect to shares held by the BVP Entities are made by the directors of Deer Ltd. acting as an investment committee.

(4) HBM BioCapital II LP is a holder of more than 5% of our voting securities. Axel Bolte, a member of our board of directors, is an investment advisor to HBM Partners AG, which provides investment advisory services to HBM BioCapital II Management Ltd., the general partner of HBM BioCapital II LP.

Series C Financing

On November 25, 2015 and December 17, 2015, we issued and sold to investors an aggregate of 20,000,000 shares of our Series C preferred stock, at a price per share of $2.65, for aggregate cash consideration of $53,000,000, pursuant to a stock purchase agreement initially entered into with investors on November 25, 2015.

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The following table summarizes the participation in the closing of the Series C preferred stock financing by any of our directors, executive officers, holders of more than 5% of our voting securities, or any member of the immediate family of the foregoing persons.

Name	Shares of Series C Preferred Stock
Frazier Healthcare Partners VI, L.P.(1)	1,061,904
HBM BioCapital II LP(2)	587,872
Pharmstandard International S.A.(3)	1,980,105
Affiliates of Fidelity(4)	7,547,169
Affiliates of Partner Fund Management, L.P.(5)	5,660,377

(1) Frazier Healthcare Partners VI, L.P. is a holder of more than 5% of our voting securities. James N. Topper, M.D., Ph.D. is a managing general partner of Frazier Healthcare Partners, of which Frazier Healthcare Partners VI, L.P. is an affiliated fund, and is a member of our board of directors.

(2) HBM BioCapital II LP is a holder of more than 5% of our voting securities. Axel Bolte, a member of our board of directors, is an investment advisor to HBM Partners AG, which provides investment advisory services to HBM BioCapital II Management Ltd., the general partner of HBM BioCapital II LP.

(3) Pharmstandard International S.A. is a holder of more than 5% of our voting securities.

(4) Includes 6,041,631 shares of our Series C preferred stock to Fidelity Select Portfolios: Biotechnology Portfolio and 1,505,538 shares of our Series C preferred stock to Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund. These entities collectively hold more than 5% of our voting securities.

(5) Includes 2,512,794 shares of our Series C preferred stock to PFM Healthcare Opportunities Master Fund, L.P., 774,365 shares of our Series C preferred stock to PFM Healthcare Emerging Growth Master Fund, L.P. and 2,373,218 shares of our Series C preferred stock to Partner Investments, L.P. These entities collectively hold more than 5% of our voting securities.

Indemnification Agreements

We have entered into agreements to indemnify our directors and executive officers to the maximum extent allowed under Delaware law. Subject to the provisions of these agreements, these agreements, among other things, indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of us or that person's status as a member of our board of directors.

Agreements with our Stockholders

In connection with our preferred stock financings, we entered into an investor rights agreement, a right of first refusal and co-sale agreement, and voting agreement, in each case, with the purchasers of our preferred stock and certain holders of our common stock. Our second amended and restated right of first refusal and co-sale agreement, or ROFR Agreement, provides for rights of first refusal, co-sale and drag along rights in respect of sales by certain holders of our capital stock. Our second amended and restated voting agreement, as amended, or Voting Agreement, contains provisions with respect to the election of our board of directors and its composition.

Our second amended and restated investors' rights agreement, or Investor Rights Agreement, provides certain holders of our preferred stock with a participation right to purchase their *pro rata* share of new securities that we may propose to sell and issue, subject to certain exceptions. The Investor Rights Agreement further provides certain holders of our capital stock with the right to demand that we file a registration statement, subject to certain limitations, and to request that their shares be covered by a registration statement that we are otherwise filing. See "Description of Capital Stock—Registration Rights" for additional information regarding such registration rights.

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The rights under each of the ROFR Agreement, Voting Agreement and Investor Rights Agreement will terminate upon the closing of this offering, other than certain registration rights for certain holders of our preferred stock as provided for in the Investor Rights Agreement and described below in "Description of Capital Stock—Registration Rights."

Management and Consulting Services

During the fiscal years ended December 31, 2014, 2015, 2016 and the six months ended June 30, 2017, we incurred consulting fees to Third Rock Ventures, LLC, or TRV, in the amounts of $2,000, $52,000, $69,000 and $2,000, respectively. TRV is a management company affiliated with Third Rock Ventures II, L.P., beneficial owner of more than 5% of our voting securities. Dr. Tepper is a member of our board of directors and a partner of Third Rock Ventures, L.P.

Participation in this Offering

Certain of our existing stockholders who previously indicated an interest in purchasing shares of our common stock in this offering, including certain affiliates of our directors, have agreed to purchase an aggregate of approximately $20 million of shares of our common stock in this offering at the initial public offering price.

Related Person Transactions Policy

Our board of directors reviews and approves transactions with directors, officers and holders of 5% or more of our voting securities and their affiliates, or each, a related party. Prior to this offering, the material facts as to the related party's relationship or interest in the transaction are disclosed to our board of directors prior to their consideration of such transaction, and the transaction is not considered approved by our board of directors unless a majority of the directors who are not interested in the transaction approve the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party's relationship or interest in the transaction are disclosed to the stockholders, who must approve the transaction in good faith.

We have adopted a written related party transactions policy that such transactions must be approved by our audit committee or another independent body of our board of directors.

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PRINCIPAL STOCKHOLDERS

The following table sets forth information relating to the beneficial ownership of our common stock as of June 30, 2017 by: each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock; each of our directors; each of our named executive officers; and all directors and executive officers as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the Securities and Exchange Commission, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of June 30, 2017 through the exercise of any stock options or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person.

Certain of our existing stockholders who previously indicated an interest in purchasing shares of our common stock in this offering, including certain affiliates of our directors, have agreed to purchase an aggregate of approximately $20 million of shares of our common stock in this offering at the initial public offering price. The table below does not give effect to the purchases by such stockholders in this offering.

The percentage of shares beneficially owned before the offering is computed on the basis of 15,288,515 shares of our common stock outstanding as of June 30, 2017, which reflects the assumed conversion of all 58,208,614 of our outstanding shares of preferred stock into an aggregate of 13,945,509 shares of common stock. The percentage of shares beneficially owned after the offering is computed on the basis of 20,621,848 shares of our common stock outstanding as of June 30, 2017, which reflects the assumed conversion of all 58,208,614 shares of our outstanding shares of preferred stock into an aggregate of 13,945,509 shares of common stock and 5,333,333 shares of our common stock sold in the offering.

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Shares of our common stock that a person has the right to acquire within 60 days of June 30, 2017 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Allena Pharmaceuticals, Inc., One Newton Executive Park, Suite 202, Newton, MA 02462.

		Percentage of Shares Beneficially Owned	
Name and address of beneficial owner	Number of shares beneficially owned	Before offering	After offering
5% or greater stockholders:			
Frazier Healthcare VI, L.P.(1)	2,830,373	18.5%	13.7%
Third Rock Ventures II, L.P.(2)	2,575,964	16.8%	12.5%
Affiliates of Bessemer Venture Partners(3)	2,227,365	14.6%	10.8%
Affiliates of Fidelity(4)	1,808,137	11.8%	8.8%
HBM BioCapital II LP(5)	1,566,902	10.2%	7.6%
Affiliates of Partner Fund Management, L.P.(6)	1,356,103	8.9%	6.6%
Pharmstandard International S.A.(7)	822,982	5.4%	4.0%
Directors and executive officers:			
Alexey Margolin, Ph.D(8)	1,029,410	6.6%	4.9%
Axel Bolte	—	—	—
Stephen Kraus	—	—	—
Gino Santini(9)	31,144	*	*
Robert Tepper, M.D.(2)	2,575,964	16.8%	12.5%
James N. Topper, M.D., Ph.D.(1)	2,830,373	18.5%	13.7%
Robert Alexander, Ph.D.(10)	12,717	*	*
Louis Brenner, M.D.(11)	150,497	*	*
Edward Wholihan(12)	56,009	*	*
All executive officers and directors as a group (9 persons)	6,686,114	42.5%	31.7%

* Represents beneficial ownership of less than one percent of our outstanding common stock.

(1) Consists of (i) 1,466,805 shares of common stock issuable upon conversion of shares of Series A convertible preferred stock , (ii) 1,109,159 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock and 254,409 shares of common stock issuable upon conversion of shares of Series C convertible preferred stock. All shares are held directly by Frazier Healthcare VI, L.P. The general partner of Frazier Healthcare VI, L.P is FHM VI, LLC, a Delaware limited partnership. The general partner of FHM VI, L.P. is FHM VI, LLC, a Delaware limited liability company. Dr. Topper, a member of our board of directors, Alan Frazier, Nader Naini, Nathan Every and Patrick Heron are all of the members of FHM VI, LLC and therefore share voting and investment power with respect to the shares held by FHM VI, LLC. The members disclaim beneficial ownership of such shares except to the extent of their pecuniary interest in such shares, if any. The address of Frazier Healthcare VI, L.P. is 601 Union, Two Union Square, Suite 3200, Seattle, Washington 98101.

(2) Consists of (i) 1,466,805 shares of common stock issuable upon conversion of shares of Series A convertible preferred stock and (ii) 1,109,159 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock. All shares are held directly by Third Rock Ventures II, L.P., or TRV LP. Each of Third Rock Ventures II GP, L.P., or TRV GP, the general partner of TRV LP, TRV GP II, LLC, or TRV LLC, the general partner of TRV GP, and Mark Levin, Kevin Starr and Robert Tepper, the managers of TRV LLC, may be deemed to share voting and investment power over the shares held of record by TRV LP. Each of TRV GP, TRV LLC, Mark Levin, Kevin Starr and Robert Tepper disclaims beneficial ownership of all shares held by TRV LP except to the extent of their pecuniary interest therein. Dr. Tepper is a member of our board of directors. The address for TRV LP is 29 Newbury Street, 3rd Floor, Boston, MA 02116.

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(3) Consists of (i) 205,350 shares of common stock issuable upon conversion of shares of Series A convertible preferred stock held of record by Bessemer Venture Partners VII Institutional L.P., (ii) 792,074 shares of common stock issuable upon conversion of shares of Series A convertible preferred stock held of record by BVP VII Special Opportunity Fund L.P., (iii) 469,376 shares of common stock issuable upon conversion of shares of Series A convertible preferred stock held of record by Bessemer Venture Partners VII L.P., (iv) 106,479 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock held of record by Bessemer Venture Partners VII Institutional L.P., (v) 410,075 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock held of record by BVP VII Special Opportunity Fund L.P. and (vi) 243,381 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock held of record by Bessemer Venture Partners VII L.P., or collectively, the BVP Entities. Deer VII & Co. L.P., or Deer L.P., is the general partner of the BVP Entities, and Deer VII & Co. Ltd., or Deer Ltd., is the general partner of Deer L.P. Each of Deer L.P. and Deer Ltd. may be deemed to have voting and dispositive power of the shares held by the BVP Entities. J. Edmund Colloton, David J. Cowan, Byron B. Deeter, Robert P. Goodman, Jeremy S. Levine and Robert M. Stavis are the directors of Deer Ltd. Investment and voting decisions with respect to the shares held by the BVP Entities are made by the directors of Deer VII Ltd. acting as an investment committee. Mr. Kraus has a passive economic interest in the shares held by the BVP Entities through an interest in (1) Bessemer Venture Partners VII L.P. and (2) Deer L.P. Mr. Kraus, a member of our board of directors, disclaims beneficial ownership of such shares held by the BVP Entities except to the extent of his pecuniary interest in such shares. The address for each of these entities is c/o Bessemer Venture Partners, 1865 Palmer Avenue, Suite 104, Larchmont, New York 10538.

(4) Consists of (i) 1,447,443 shares of common stock issuable upon conversion of shares of Series C convertible preferred stock held by Fidelity Select Portfolios: Biotechnology Portfolio, or FSP, and (ii) 360,694 shares of common stock issuable upon conversion of shares of Series C convertible preferred stock held by Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund or FAS. FSP and FAS are managed by direct or indirect subsidiaries of FMR LLC. Abigail P. Johnson is a Director, the Vice Chairman, the Chief Executive Officer and the President of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act, or the Fidelity Funds, advised by Fidelity Management & Research Company, or FMR Co, a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. FMR Co carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. The address of FSP is Mag & Co., c/o Brown Brothers Harriman & Co., Attn: Corporate Actions /Vault, 140 Broadway, New York, NY 10005 and the address of FAS is State Street Bank & Trust, PO Box 5756, Boston, Massachusetts 02206, Attn: Bangle & Co fbo Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund.

(5) Consists of (i) 1,426,061 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock and (ii) 140,841 shares of common stock issuable upon conversion of shares of Series C convertible preferred stock. All shares are held directly by HBM BioCapital II LP. The board of directors of HBM BioCapital II Management Ltd., the general partner of the HBM BioCapital II LP, has sole voting and investment power with respect to such shares. The board of directors of HBM BioCapital II Management Ltd. consists of Mark Wanless, Andrew Wignall and Jim Millen, none of whom has individual voting or investment power with respect to the shares. The address for HBM BioCapital II LP is c/o HBM BioCapital II Management Ltd., Aztec Group House 11-15, Seaton Place, St. Helier JE4 0QH, Jersey. Mr. Bolte, a member of our board of directors, is an investment advisor to HBM Partners AG, which provides investment advisory services to HBM BioCaital II Management Ltd. Mr. Bolte has no voting or investment power over the shares held by HBM BioCaptial II LP.

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(6) Consists of (i) 602,011 shares of common stock issuable upon conversion of shares of Series C convertible preferred stock held of record by PFM Healthcare Opportunities Master Fund, L.P., or HCOMF, (ii) 185,521 shares of common stock issuable upon conversion of shares of Series C convertible preferred stock held of record by PFM Healthcare Emerging Growth Master Fund, L.P., or HCEMG, and (iii) 568,571 shares of common stock issuable upon conversion of shares of Series C convertible preferred stock held of record by Partner Investments, L.P., or PI. Partner Fund Management, L.P., or PFM, is the investment advisor of HCEMG and HCOMF. Partner Investment Management, L.P., or PIM, is the investment advisor of PI. Partner Fund Management GP, LLC, or PFM-GP, and Partner Investment Management GP, LLC, or PIM-GP, are, respectively, the general partners of PFM and PIM. Brian Grossman and Christopher James are co-managing members of PFM-GP and PIM-GP. The address of the principal business office of such entities and persons is c/o Partner Fund Management, L.P., 4 Embarcadero Center, Suite 3500, San Francisco, CA 94111.

(7) Consists of (i) 348,592 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock and (ii) 474,390 shares of common stock issuable upon conversion of shares of Series C convertible preferred stock. All shares are held directly by Pharmstandard International S.A. Pharmstandard International S.A is a wholly owned subsidiary of Joint Stock Company "Pharmstandard." As the parent entity, Joint Stock Company "Pharmstandard" has voting and investment control over the shares of the Company held by Pharmstandard International S.A. The address of Pharmstandard is 65, Boulevard Grande Duchesse Charlotte, L-1331 Luxembourg, Grand Duchy of Luxembourg.

(8) Includes (i) 808,752 shares of common stock and (ii) options to purchase 220,658 shares of common stock presently exercisable or exercisable within sixty (60) days of June 30, 2017.

(9) Includes (i) 15,572 shares of common stock and (ii) options to purchase 15,572 shares of common stock presently exercisable or exercisable within sixty (60) days of June 30, 2017.

(10) Includes options to purchase 12,717 shares of common stock presently exercisable or exercisable within sixty (60) days of June 30, 2017.

(11) Includes options to purchase 150,497 shares of common stock presently exercisable or exercisable within sixty (60) days of June 30, 2017.

(12) Includes options to purchase 56,009 shares of common stock presently exercisable or exercisable within sixty (60) days of June 30, 2017.

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DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our restated certificate of incorporation and amended and restated bylaws, which will be effective upon consummation of this offering. The descriptions of the common stock and preferred stock give effect to changes to our capital structure that will occur immediately prior to the closing of this offering. We refer in this section to our restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

General

Upon completion of this offering, our authorized capital stock will consist of 125,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share, all of which shares of preferred stock will be undesignated.

As of June 30, 2017, 15,288,515 shares of our common stock were outstanding and held by 28 stockholders of record. This amount assumes the conversion of all outstanding shares of our preferred stock into common stock, which will occur immediately prior to the consummation of this offering. In addition, as of June 30, 2017, we had outstanding options to purchase 1,394,299 shares of our common stock, at a weighted average exercise price of $1.41 per share, 653,187 of which were exercisable and outstanding warrants to purchase 43,265 shares of our common stock, at a weighted average exercise price of $5.55.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by the board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred Stock

Immediately prior to the consummation of this offering, all outstanding shares of our preferred stock will be converted into shares of our common stock and our restated certificate of incorporation will be amended and restated to delete all references to such shares of preferred stock. Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plans to issue any shares of preferred stock.

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Registration Rights

Upon the closing of this offering, the holders of our registrable shares, as described in our second amended and restated investors' rights agreement, or the Investor Rights Agreement, are entitled to rights with respect to the registration of these shares under the Securities Act as hereinafter described. These rights are provided under the terms of the Investor Rights Agreement, and include demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand Registration Rights

Upon the closing of this offering, certain holders of shares of our common stock, including shares issuable upon the conversion of preferred stock or their permitted transferees, are entitled to demand registration rights. Under the terms of the Investor Rights Agreement, we will be required, upon the written request of holders of at least 60% of the shares of our common stock issued upon conversion of our preferred stock upon the consummation of this offering, or a lesser percent if the anticipated net proceeds of the offering would exceed $15 million, to effect the registration of our common shares issued upon conversion of our preferred stock upon consummation of this offering, subject to certain exceptions. We are required to effect only one registration pursuant to this provision of the Investor Rights Agreement. A demand for registration may not be made until the earlier of November 25, 2018 and 180 days after the closing of this offering. An aggregate of 13,945,509 shares of common are entitled to these demand registration rights.

Form S-3 Registration Rights

Upon the closing of this offering, certain holders of shares of our common stock issued upon the conversion of our preferred stock or their permitted transferees are also entitled to short form registration rights. If we are eligible to file a registration statement on Form S-3, upon the written request of holders of at least 40% of our common stock issued upon conversion of our preferred stock upon consummation of this offering to register shares with an anticipated aggregate offering price of at least $2,000,000, we will be required to use our commercially reasonable efforts to effect a registration of such shares, subject to certain exceptions. We are required to effect up to two registrations in any twelve month period pursuant to this provision of the Investor Rights Agreement. An aggregate of 13,945,509 shares of common stock are entitled to these Form S-3 registration rights.

Piggyback Registration Rights

Upon the closing of this offering, certain holders of shares of our common stock issued upon the conversion of our preferred stock or their permitted transferees are entitled to piggyback registration rights. If we propose to register any of our securities, either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions, the managing underwriter may limit the number of shares included in the underwritten offering if it concludes that marketing factors require such a limitation. An aggregate of 13,945,509 shares of common stock are entitled to these piggyback registration rights.

Indemnification

The Investor Rights Agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

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Expiration of Registration Rights

The registration rights granted under the Investor Rights Agreement will terminate on the earliest of (i) a deemed liquidation event, as defined in the Investor Rights Agreement, and (ii) the fifth anniversary of the closing of this offering.

Anti-Takeover Effects of Our Certificate of Incorporation and Our Bylaws

Our certificate of incorporation and bylaws will contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors and which may have the effect of delaying, deferring or preventing a future takeover or change in control of the company unless such takeover or change in control is approved by the board of directors.

These provisions include:

Classified Board. Our certificate of incorporation will provide that our board of directors will be divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors will be elected each year. The classification of directors will have the effect of making it more difficult for stockholders to change the composition of our board. Our certificate of incorporation will also provide that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors. Upon completion of this offering, we expect that our board of directors will have seven members.

Action by Written Consent; Special Meetings of Stockholders. Our certificate of incorporation will provide that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our certificate of incorporation and the bylaws will also provide that, except as otherwise required by law, special meetings of the stockholders can be called only by or at the direction of the board of directors pursuant to a resolution adopted by a majority of the total number of directors. Stockholders will not be permitted to call a special meeting or to require the board of directors to call a special meeting.

Removal of Directors. Our certificate of incorporation will provide that our directors may be removed only for cause by the affirmative vote of at least 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors, voting together as a single class, at a meeting of the stockholders called for that purpose. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board.

Advance Notice Procedures. Our bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the bylaws will not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

Super Majority Approval Requirements. The Delaware General Corporation Law generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws requires

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a greater percentage. A majority vote of our board of directors or the affirmative vote of holders of at least 75% of the total votes of the outstanding shares of our capital stock entitled to vote with respect thereto, voting together as a single class, will be required to amend, alter, change or repeal the bylaws. In addition, the affirmative vote of the holders of at least 75% of the total votes of the outstanding shares of our capital stock entitled to vote with respect thereto, voting together as a single class, will be required to amend, alter, change or repeal, or to adopt any provisions inconsistent with, any of the provisions in our certificate of incorporation relating to amendments to our certificate of incorporation and bylaws and as described under "Action by Written Consent; Special Meetings of Stockholders", "Classified Board" and "Removal of Directors" above. This requirement of a supermajority vote to approve amendments to our bylaws and certificate of incorporation could enable a minority of our stockholders to exercise veto power over any such amendments.

Authorized but Unissued Shares. Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital and corporate acquisitions. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Exclusive Forum. Our certificate of incorporation will provide that, subject to limited exceptions, the state or federal courts located in the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable.

Section 203 of the Delaware General Corporation Law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law, or Section 203. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 75% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved

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by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, Massachusetts 02021, and its telephone number is (800) 962-4284.

Listing

Our common stock is listed on The Nasdaq Global Select Market under the symbol "ALNA".

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SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of our common stock, including shares issued upon the exercise of outstanding options and warrants, in the public market after this offering, or the perception that those sales may occur, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital at a time and price we deem appropriate. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after completion of this offering due to contractual and legal restrictions on resale described below.

Based on the number of shares of our common stock outstanding as of June 30, 2017, upon the closing of this offering and assuming (1) the conversion of our outstanding preferred stock into common stock, (2) no exercise of the underwriters' option to purchase additional shares of common stock, and (3) no exercise of outstanding options and warrants, we would have had outstanding an aggregate of 20,621,848 shares of common stock. Of these shares, all of the shares of common stock to be sold in this offering, and any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our affiliates as such term is defined in Rule 144 of the Securities Act of 1933, as amended, or the Securities Act.

Rule 144

In general, a person who has beneficially owned restricted stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Securities Exchange Act of 1934, as amended, or the Exchange Act, periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any six-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares then outstanding, which will equal approximately 206,218 shares immediately after this offering assuming no exercise of the underwriters' option to purchase additional shares, based on the number of shares outstanding as of June 30, 2017; or
- the average weekly trading volume of our common stock on The Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144 of the Securities Act, or Rule 144.

Rule 701

Rule 701 under the Securities Act, or Rule 701, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below in the section titled "Underwriting" included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

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Lock-up Agreements

All of our directors and executive officers and substantially all holders of our shares, who collectively held 15,288,515 shares of common stock as of June 30, 2017, have signed a lock-up agreement which prevents them from selling any of our common stock or any securities convertible into or exercisable or exchangeable for common stock for a period of not less than 180 days from the date of this prospectus, subject to certain exceptions, without the prior written consent of Credit Suisse Securities (USA) LLC and Jefferies LLC, as representatives of the underwriters. The representatives may in their sole discretion release some or all of the common stock and other securities subject to lock-up agreements prior to the expiration of the 180-day period. When determining whether or not to release shares from the lock-up agreements, Credit Suisse Securities (USA) LLC and Jefferies LLC will consider, among other factors, the stockholder's reasons for requesting the release and the number of shares of common stock or other securities for which the release is being requested.

Registration Rights

Upon completion of this offering, the holders of 13,945,509 shares of common stock or their transferees will be entitled to various rights with respect to registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See the section titled "Description of Capital Stock—Registration Rights" for additional information.

Stock Option Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our shares issued or reserved for issuance under our stock option plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above. Such registration statement on Form S-8 will cover 3,756,504 shares.

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MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

The following is a general discussion of the material U.S. federal income and estate tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is not a "United States person" or a partnership for U.S. federal income tax purposes. A United States person is any of the following:

- an individual citizen or resident (for U.S. federal income tax purposes) of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a U.S. court and which has one or more United States persons who have the authority to control all substantial decisions of the trust, or (2) that has a valid election in effect under applicable Treasury regulations to be treated as a United States person for U.S. federal income tax purposes.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

An individual may be treated as a resident instead of a nonresident of the United States in any calendar year for U.S. federal income tax purposes if the individual was present in the United States for at least 31 days in that calendar year and for an aggregate of at least 183 days during the three-year period ending with the current calendar year. For purposes of this calculation, all of the days present in the current year, one-third of the days present in the immediately preceding year and one-sixth of the days present in the second preceding year are counted, subject to certain exceptions not discussed herein. The tax treatment of U.S. citizens and residents (including individuals who meet the foregoing substantial presence test) who hold shares of our common stock is not discussed in this summary.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset, generally property held for investment.

This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any aspects of U.S. state, local or non-U.S. taxes, the alternative minimum tax, or gift tax.

This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, including without limitation:

- insurance companies;

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- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities or currencies;
- pension plans;
- controlled foreign corporations;
- passive foreign investment companies;
- persons that have a functional currency other than the U.S. dollar;
- owners deemed to sell our common stock under the constructive sale provisions of the Code;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- owners in special situations, such as those who have elected to mark securities to market, or those that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- certain U.S. expatriates.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

Distributions on Our Common Stock

Distributions, if any, on our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be allocated ratably among each share of common stock with respect to which the distribution is paid and treated as a tax-free return of the non-U.S. holder's investment, up to such holder's adjusted tax basis in the common stock. A holder's adjusted tax basis in a share of our common stock is generally the purchase price of such share, reduced by the amount of any such tax-free returns of capital. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "Gain on sale, exchange or other disposition of our common stock." Any such distributions will also be subject to the discussion below under the section titled "Withholding and Information Reporting Requirements—FATCA."

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements, including delivery of a properly executed IRS Form W-8ECI. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to United States persons. Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to (i) provide a properly

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executed IRS Form W-8BEN or W-8BEN-E (or successor form) and certify under penalties of perjury that such holder is not a United States person and is eligible for treaty benefits, or (ii) if our common stock is held through certain foreign intermediaries, satisfy applicable certification and other requirements. Special certification and other requirements apply to certain non-U.S. holders that act as intermediaries (including partnerships). Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. tax return with the IRS.

Gain on Sale, Exchange or Other Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and FATCA (as defined below), in general, a non-U.S. holder will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to United States persons and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on Our Common Stock" also may apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to U.S. federal income tax at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses (not including any capital loss carryovers) of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such disposition and capital losses; or
- we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation and the foregoing exception does not apply, then a purchaser will be required to withhold 15% of the proceeds payable to a non-U.S. holder from a sale of our common stock and the non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to United States persons. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United

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States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in "Distributions on Our Common Stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder (usually on IRS Form W-8BEN or W-8BEN-E) and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder if the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

Withholding and Information Reporting Requirements—FATCA

Sections 1471 through 1474 of the Code, commonly referred to as FATCA, generally impose a U.S. federal withholding tax at a rate of 30% on payments of dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Under applicable U.S. Treasury regulations, withholding under FATCA currently applies to payments of dividends on our common stock, and will apply to payments of gross proceeds from a sale or other disposition of our common stock made after December 31, 2018. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of the tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their own tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock.

United States Federal Estate Tax

Shares of our common stock that are owned or treated as owned at the time of death by an individual who is not a citizen or resident of the United States, as specifically defined for U.S. federal estate tax purposes, are considered U.S. situs assets and will be included in the individual's gross estate for U.S. federal estate tax purposes. Such shares, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

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UNDERWRITING

Under the terms and subject to the conditions contained in an underwriting agreement dated November 1, 2017, we have agreed to sell to the underwriters named below, for whom Credit Suisse Securities (USA) LLC, Jefferies LLC and Cowen and Company, LLC are acting as representatives (the "Representatives"), the following respective numbers of shares of common stock:

Underwriter	Number of Shares
Credit Suisse Securities (USA) LLC	1,920,000
Jefferies LLC	1,653,333
Cowen and Company, LLC	1,226,667
Wedbush Securities Inc.	533,333
Total	5,333,333

The underwriting agreement provides that the underwriters are obligated to purchase all the shares of common stock in the offering if any are purchased, other than those shares covered by the option described below. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may be increased or the offering may be terminated.

We have granted the underwriters a 30-day option to purchase up to additional 800,000 shares at the initial public offering price less the underwriting discounts and commissions. The option may be exercised only to cover any over-allotments of common stock.

Certain of our existing stockholders who previously indicated an interest in purchasing shares of our common stock in this offering, including certain affiliates of our directors, have agreed to purchase an aggregate of approximately $20 million of shares of our common stock in this offering at the initial public offering price. Any such purchases, if completed, would be made on the same terms as the shares that are sold to the public generally and not pursuant to any pre-existing contractual rights or obligations. Whether or not these investors purchase any or all of the shares for which they have agreed to purchase will not affect the underwriters' commitment to purchase the shares of common stock offered by us if the underwriters purchase any shares.

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations among us and the representatives and will not necessarily reflect the market price of the common stock following this offering. The principal factors that were considered in determining the initial public offering price included:

- the information presented in this prospectus and otherwise available to the underwriters;
- the history of, and prospects for, the industry in which we will compete;
- the ability of our management;
- the prospects for our future earnings;
- the present state of our development, results of operations and our current financial condition;
- the general condition of the securities markets at the time of this offering; and
- the recent market prices of, and the demand for, publicly traded common stock of generally comparable companies.

We cannot assure you that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to this offering or that an active trading market for the common stock will develop and continue after this offering.

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The underwriters propose to offer the shares of common stock initially at the initial public offering price on the cover page of this prospectus and to selling group members at that price less a selling concession of up to $0.588 per share. After the initial offering of the shares of common stock, the underwriters may change the initial public offering price and selling concession. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

The following table summarizes the compensation and estimated expenses that we will pay:

	Per Share		Total	
	Without Option	With Option	Without Option	With Option
Underwriting Discounts and Commissions				
Paid by us	$ 0.98	$ 0.98	$5,226,666	$6,010,666
Expenses payable by us	$ 0.56	$ 0.49	$3,000,000	$3,000,000

We estimate that our out-of-pocket expenses for this offering will be approximately $3.0 million. We have also agreed to reimburse the underwriters for certain of their expenses in an amount up to $30,000 as set forth in the underwriting agreement.

The Representatives have informed us that they do not expect sales to accounts over which the underwriters have discretionary authority to exceed 5% of the shares of common stock being offered.

In connection with this offering, we agreed that, subject to certain exceptions, we will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, or file with the SEC a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, without the prior written consent of Credit Suisse Securities (USA) LLC and Jefferies LLC for a period of 180 days after the date of this prospectus.

Each of our officers, directors and holders of substantially all of our outstanding stock agreed in connection with this offering that they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, enter into a transaction that would have the same effect, or enter into any swap, hedge or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock, whether any of these transactions are to be settled by delivery of our common stock or other securities, in cash or otherwise, or publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement, without, in each case, the prior written consent of Credit Suisse Securities (USA) LLC and Jefferies LLC for a period of 180 days after the date of this prospectus.

Credit Suisse Securities (USA) LLC and Jefferies LLC, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release the common stock and other securities from lock-up agreements, Credit Suisse Securities (USA) LLC and Jefferies LLC will consider, among other factors, the holder's reasons for requesting the release and the number of shares of common stock or other securities for which the release is being requested.

We have agreed to indemnify the underwriters against liabilities under the Securities Act, or contribute to payments that the underwriters may be required to make in that respect.

Our common stock is listed on the Nasdaq Global Select Market under the symbol "ALNA."

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The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have from time to time performed, and may in the future perform, various financial advisory, commercial banking and investment banking services for us and for our affiliates in the ordinary course of business for which they have received and would receive customary compensation.

In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investments and securities activities may involve securities and/or instruments of the issuer. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

In connection with the offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions, penalty bids and passive market making in accordance with Regulation M under the Exchange Act.

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- Over-allotment involves sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in their option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares in their option to purchase additional shares. The underwriters may close out any covered short position by either exercising their option to purchase additional shares and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. If the underwriters sell more shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.
- In passive market making, market makers in the common stock who are underwriters or prospective underwriters may, subject to limitations, make bids for or purchases of our common stock until the time, if any, at which a stabilizing bid is made.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result the price of our common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the Nasdaq Global Select Market or otherwise and, if commenced, may be discontinued at any time.

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A prospectus in electronic format may be made available on the web sites maintained by one or more of the underwriters, or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representatives may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations.

Selling Restrictions

Notice to Prospective Investors in Switzerland

This document is not intended to constitute an offer or solicitation to purchase or invest in the securities described herein. The securities may not be publicly offered, sold or advertised, directly or indirectly, in, into or from Switzerland and will not be listed on the SIX Swiss Exchange or on any other exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the securities constitutes a prospectus as such term is understood pursuant to article 652a or article 1156 of the Swiss Code of Obligations or a listing prospectus within the meaning of the listing rules of the SIX Swiss Exchange or any other regulated trading facility in Switzerland, and neither this document nor any other offering or marketing material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, nor the Company nor the securities have been or will be filed with or approved by any Swiss regulatory authority. The securities are not subject to the supervision by any Swiss regulatory authority, e.g., the Swiss Financial Markets Supervisory Authority FINMA ("FINMA"), and investors in the securities will not benefit from protection or supervision by such authority.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State"), each underwriter represents and agrees that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, it has not made and will not make an offer of securities which are the subject of the offering contemplated by this prospectus to the public in that Relevant Member State other than:

(a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression Prospectus Directive means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

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Notice to Prospective Investors in the United Kingdom

Each of the underwriters severally represents warrants and agrees as follows:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (FSMA) received by it in connection with the issue or sale of the securities in circumstances in which Section 21 of the FSMA does not apply to us; and

(b) it has complied with, and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

Notice to Canadian Residents

Resale Restrictions

The distribution of our common stock in Canada is being made only in the provinces of Ontario, Quebec, Alberta and British Columbia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of our common stock in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the securities.

Representations of Canadian Purchasers

By purchasing our common stock in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase our common stock without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106—Prospectus Exemptions,
- the purchaser is a "permitted client" as defined in National Instrument 31-103—Registration Requirements, Exemptions and Ongoing Registrant Obligations, where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

Conflicts of Interest

Canadian purchasers are hereby notified that the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105—Underwriting Conflicts from having to provide certain conflict of interest disclosure in this document.

Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the offering memorandum (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

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Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

Taxation and Eligibility for Investment

Canadian purchasers of our common stock should consult their own legal and tax advisors with respect to the tax consequences of an investment in the common stock in their particular circumstances and about the eligibility of the common stock for investment by the purchaser under relevant Canadian legislation.

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LEGAL MATTERS

The validity of the common stock offered in this prospectus will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Davis Polk & Wardwell LLP, New York, New York, is serving as counsel to the underwriters.

EXPERTS

The consolidated financial statements of Allena Pharmaceuticals, Inc. at December 31, 2015 and 2016, and for the years then ended, appearing in this prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-220857) under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information with respect to us and the common stock offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits and schedules filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street N.E., Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from such offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address is www.sec.gov.

We are subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above.

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Allena Pharmaceuticals, Inc.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of
Allena Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Allena Pharmaceuticals, Inc. as of December 31, 2015 and 2016, and the related consolidated statements of operations and comprehensive loss, stockholders' (deficit) equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Allena Pharmaceuticals, Inc. at December 31, 2015 and 2016, and the consolidated results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts
August 18, 2017,
except for Note 16, as to which the date is October 23, 2017

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Allena Pharmaceuticals, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2015	December 31, 2016	June 30, 2017 (unaudited)	Pro forma June 30, 2017 (unaudited)
Assets				
Current assets:				
Cash and cash equivalents	$ 69,011	$ 25,250	$ 34,713	$ 34,713
Short-term investments	—	23,505	3,249	3,249
Prepaid expenses and other current assets	863	520	350	350
Total current assets	69,874	49,275	38,312	38,312
Property and equipment, net	89	169	153	153
Other assets	45	35	114	114
Total assets	$ 70,008	$ 49,479	$ 38,579	$ 38,579
Liabilities, Convertible Preferred Stock and Stockholders' (Deficit) Equity				
Current liabilities:				
Accounts payable	$ 1,959	$ 1,464	$ 1,236	$ 1,236
Loan payable, net of discount	2,253	176	2,088	2,088
Accrued expenses	927	1,610	846	846
Total current liabilities	5,139	3,250	4,170	4,170
Loan payable, net of current portion and discount	3,932	9,409	7,553	7,553
Warrants for the purchase of shares subject to redemption	68	267	299	—
Other liabilities	180	103	210	210
Total liabilities	9,319	13,029	12,232	11,933
Commitments and contingencies (Note 13)				
Series A convertible preferred stock, $0.001 par value; 18,510,200 shares authorized at December 31, 2015 and 2016 and June 30, 2017 (unaudited); 18,367,344 shares issued and outstanding at December 31, 2015 and 2016 and June 30, 2017 (unaudited) (aggregate liquidation preference of $18,000 at December 31, 2016 and June 30, 2017 (unaudited)); no shares authorized, issued or outstanding, pro forma (unaudited)	17,959	17,967	17,971	—
Series B convertible preferred stock, $0.001 par value; 21,428,572 shares authorized at December 31, 2015 and 19,841,270 shares authorized at December 31, 2016 and June 30, 2017 (unaudited); 19,841,270 shares issued and outstanding at December 31, 2015 and 2016 and June 30, 2017 (unaudited) (aggregate liquidation preference of $25,000 at December 31, 2016 and June 30, 2017 (unaudited)); no shares authorized, issued or outstanding, pro forma (unaudited)	24,913	24,931	24,939	—
Series C convertible preferred stock, $0.001 par value; 20,000,000 shares authorized at December 31, 2015 and 20,037,736 shares authorized at December 31, 2016 and June 30, 2017 (unaudited); 20,000,000 shares issued and outstanding at December 31, 2015 and 2016 and June 30, 2017 (unaudited) (aggregate liquidation preference of $53,000 at December 31, 2016 and June 30, 2017 (unaudited)); no shares authorized, issued or outstanding, pro forma (unaudited)	52,786	52,829	52,851	—
Stockholders' (deficit) equity:				
Common stock, $0.001 par value; 75,000,000 shares authorized at December 31, 2015 and 2016 and June 30, 2017 (unaudited); 1,316,615, 1,341,385 and 1,343,006 shares issued at December 31, 2015 and 2016 and June 30, 2017 (unaudited), respectively; 1,315,940, 1,341,385 and 1,343,006 shares outstanding at December 31, 2015 and 2016 and June 30, 2017 (unaudited), respectively; 15,288,515 shares issued and outstanding, pro forma at June 30, 2017 (unaudited)	1	1	1	15
Additional paid-in capital	830	1,031	1,195	97,241
Accumulated other comprehensive loss	—	(2)	—	—
Accumulated deficit	(35,800)	(60,307)	(70,610)	(70,610)
Total stockholders' (deficit) equity	(34,969)	(59,277)	(69,414)	26,646
Total liabilities, convertible preferred stock and stockholders' (deficit) equity	$ 70,008	$ 49,479	$ 38,579	$ 38,579

See accompanying notes.

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Allena Pharmaceuticals, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Years Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
			(unaudited)	
Operating expenses:				
Research and development	$ 11,540	$ 20,103	$ 10,025	$ 7,809
General and administrative	2,365	4,083	2,057	2,208
Total operating expenses	13,905	24,186	12,082	10,017
Other income (expense):				
Interest income (expense), net	(335)	(200)	(71)	(255)
Other income (expense), net	(7)	(121)	1	(31)
Other income (expense), net	(342)	(321)	(70)	(286)
Net loss	$ (14,247)	$ (24,507)	$ (12,152)	$ (10,303)
Net loss per share attributable to common stockholders—basic and diluted	$ (11.35)	$ (18.35)	$ (9.11)	$ (7.70)
Weighted-average common shares outstanding—basic and diluted	1,258,123	1,339,254	1,337,100	1,342,628
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)		$ (1.59)		$ (0.67)
Pro forma weighted-average common shares outstanding—basic and diluted (unaudited)		15,284,763		15,288,137
Net loss	$ (14,247)	$ (24,507)	$ (12,152)	$ (10,303)
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	—	(2)	25	2
Total other comprehensive income (loss)	—	(2)	25	2
Comprehensive loss	$ (14,247)	$ (24,509)	$ (12,127)	$ (10,301)

See accompanying notes.

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Allena Pharmaceuticals, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' (Deficit) Equity
(in thousands, except share amounts)

	Series A convertible preferred stock		Series B convertible preferred stock		Series C convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' (deficit) equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2014	18,367,344	$ 17,948	19,841,270	$ 24,891	—	$ —	1,135,653	$ 1	$ 650	$ —	$ (21,553)	$ (20,902)
Issuance of Series C convertible preferred stock, net of issuance costs of $218	—	—	—	—	20,000,000	52,782	—	—	—	—	—	—
Exercise of common stock options	—	—	—	—	—	—	17,394	—	7	—	—	7
Vesting of restricted common stock	—	—	—	—	—	—	162,893	—	3	—	—	3
Accretion of convertible preferred stock to redemption value	—	11	—	22	—	4	—	—	(37)	—	—	(37)
Stock-based compensation	—	—	—	—	—	—	—	—	207	—	—	207
Net loss	—	—	—	—	—	—	—	—	—	—	(14,247)	(14,247)
Balance at December 31, 2015	18,367,344	17,959	19,841,270	24,913	20,000,000	52,786	1,315,940	1	830	—	(35,800)	(34,969)
Exercise of common stock options	—	—	—	—	—	—	24,770	—	19	—	—	19
Vesting of restricted common stock	—	—	—	—	—	—	675	—	—	—	—	—
Accretion of convertible preferred stock to redemption value	—	8	—	18	—	43	—	—	(69)	—	—	(69)
Stock-based compensation	—	—	—	—	—	—	—	—	251	—	—	251
Change in unrealized gain (loss) on available for sale investments	—	—	—	—	—	—	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	—	—	—	—	—	—	(24,507)	(24,507)
Balance at December 31, 2016	18,367,344	17,967	19,841,270	24,931	20,000,000	52,829	1,341,385	1	1,031	(2)	(60,307)	(59,277)
Exercise of common stock options (unaudited)	—	—	—	—	—	—	1,621	—	2	—	—	2
Accretion of convertible preferred stock to redemption value (unaudited)	—	4	—	8	—	22	—	—	(34)	—	—	(34)
Stock-based compensation (unaudited)	—	—	—	—	—	—	—	—	196	—	—	196

Change in unrealized gain (loss) on available for sale investments (unaudited)	—	—	—	—	—	—	—	—	—	2	—	2
Net loss (unaudited)	—	—	—	—	—	—	—	—	—	—	(10,303)	(10,303)
Balance at June 30, 2017 (unaudited)	18,367,344	17,971	19,841,270	24,939	20,000,000	52,851	1,343,006	1	1,195	—	(70,610)	(69,414)
Conversion of preferred stock into common stock (unaudited)	(18,367,344)	(17,971)	(19,841,270)	(24,939)	(20,000,000)	(52,851)	13,945,509	14	95,747	—	—	95,761
Conversion of warrant liability to equity (unaudited)	—	—	—	—	—	—	—	—	299	—	—	299
Balance at June 30, 2017 pro forma (unaudited)	—	$ —	—	$ —	—	$ —	15,288,515	$ 15	$ 97,241	$ —	$ (70,610)	$ 26,646

See accompanying notes.

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Allena Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
			(unaudited)	
Cash flows from operating activities:				
Net loss	$ (14,247)	$ (24,507)	$ (12,152)	$ (10,303)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation expense	207	251	99	196
Depreciation expense	98	46	21	34
Non-cash interest expense	167	204	62	163
Amortization of premium on investments	—	153	71	33
Loss on disposal of equipment	7	—	—	—
Change in fair value of warrant liability	36	132	3	32
Changes in assets and liabilities:				
Prepaid expenses and other current assets	(639)	343	353	205
Other assets	—	—	—	(114)
Accounts payable	1,001	(525)	1,514	(190)
Accrued expenses	219	689	(187)	(764)
Other liabilities	(24)	(180)	(175)	—
Net cash used in operating activities	(13,175)	(23,394)	(10,391)	(10,708)
Cash flows from investing activities:				
Purchases of property and equipment	—	(102)	(14)	(56)
Purchases of investments	—	(53,210)	(39,170)	(1,247)
Maturities of investments	—	29,550	5,500	21,472
Sale of property and equipment	5	—	—	—
Net cash provided by (used in) investing activities	5	(23,762)	(33,684)	20,169
Cash flows from financing activities:				
Proceeds from the sale of Series C convertible preferred stock, net of issuance costs	52,782	—	—	—
Proceeds from exercise of stock options	7	19	19	2
Proceeds from loan payable	3,250	10,000	7,500	—
Repayment of loan payable	(744)	(6,256)	(6,256)	—
Debt issuance costs paid	—	(368)	(368)	—
Net cash provided by financing activities	55,295	3,395	895	2
Net increase (decrease) in cash and cash equivalents	42,125	(43,761)	(43,180)	9,463
Cash and cash equivalents, beginning of period	26,886	69,011	69,011	25,250
Cash and cash equivalents, end of period	$ 69,011	$ 25,250	$ 25,831	$ 34,713
Supplemental disclosure of non-cash activities:				
Cash paid for interest	$ 193	$ 472	$ 157	$ 212
Property and equipment purchases included in accounts payable	$ 9	$ 38	$ —	$ —
Issuance of warrants in connection with loan payable	$ 7	$ 67	$ 45	$ —
Accretion of convertible preferred stock to redemption value	$ 37	$ 69	$ 34	$ 34

See accompanying notes.

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Allena Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
(information as of June 30, 2017 and for the six months ended June 30, 2017 and 2016 is unaudited)

1. Organization and Basis of Presentation

Allena Pharmaceuticals, Inc. (the "Company") is a late-stage clinical biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders. The Company is focused on metabolic disorders that result in excess accumulation of certain metabolites that can cause kidney stones, damage the kidney, and potentially lead to chronic kidney disease ("CKD"), and end-stage renal disease. The Company's lead product candidate, ALLN-177, is a first-in-class, oral enzyme therapeutic that it is developing for the treatment of hyperoxaluria, a metabolic disorder commonly associated with kidney stones, CKD and other serious kidney diseases. The Company was incorporated under the laws of the State of Delaware on June 24, 2011 and is located in Newton, Massachusetts.

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations, reliance on third party manufacturers, ability to transition from pilot-scale manufacturing to large-scale production of products and the need to obtain adequate additional financing to fund the development of its product candidates.

The Company has an accumulated deficit of $70.6 million at June 30, 2017, and will require substantial additional capital to fund operations. The future success of the Company is dependent on its ability to identify and develop its product candidates and ultimately upon its ability to attain profitable operations. At June 30, 2017, the Company had $38.0 million of cash, cash equivalents and investments.

The Company believes its cash, cash equivalents and investments as of June 30, 2017 will be sufficient to fund the Company's operating plan for a period of at least one year from the issuance date of the consolidated financial statements. Thereafter, the Company will be required to obtain additional funding. The Company intends to pursue a public offering of its common stock to fund future operations. If the Company is unable to complete a sufficient public offering in a timely manner, it would need to pursue other financing alternatives, such as private financing of debt or equity or collaboration agreements. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standard Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated balance sheet as of June 30, 2017, the consolidated statements of operations and comprehensive loss and of cash flows for the six months ended June 30, 2016 and 2017, and the consolidated statement of convertible preferred stock and stockholders' (deficit) equity for the six months ended June 30, 2017 are unaudited. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial

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Allena Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements (continued)
(information as of June 30, 2017 and for the six months ended June 30, 2017 and 2016 is unaudited)

position as of June 30, 2017 and the results of its operations and its cash flows for the six months ended June 30, 2016 and 2017. The financial data and other information disclosed in these notes related to the six months ended June 30, 2016 and 2017 are unaudited. The results for the six months ended June 30, 2017 are not necessarily indicative of results to be expected for the year ending December 31, 2017, any other interim periods, or any future year or period.

Unaudited Pro Forma Financial Information

The accompanying unaudited pro forma balance sheet as of June 30, 2017 has been prepared to give effect to the automatic conversion of all outstanding shares of convertible preferred stock into 13,945,509 shares of common stock as if the Company's proposed initial public offering had occurred on June 30, 2017.

In the accompanying statements of operations and comprehensive loss, the unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited basic and diluted pro forma net loss per share attributable to common stockholders does not include the effects of the accretion of issuance costs on convertible preferred stock because it assumes that the conversion of convertible preferred stock into common stock occurred on the later of the beginning of the reporting period or the issuance date of the convertible preferred stock.

The unaudited pro forma basic and diluted weighted average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2016 and the six months ended June 30, 2017 give effect to the automatic conversion of all outstanding shares of convertible preferred stock into shares of common stock as if the conversion had occurred on the later of January 1, 2016 or the issuance date of the convertible preferred stock for the year ended December 31, 2016, and on the later of January 1, 2017 or the issuance date of the convertible preferred stock for the six months ended June 30, 2017.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Allena Pharmaceuticals, Inc. and its wholly owned subsidiaries Allena Pharmaceuticals Security Corporation ("Security Corporation"), which was incorporated in December 2014, and Allena Pharmaceuticals Ireland Limited, which was incorporated in March 2017. All intercompany transactions and balances have been eliminated.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. On an ongoing basis, the Company's management evaluates its estimates, which include but are not limited to management's judgments of accrued expenses, fair value of common stock, valuation of share-based awards, fair value of warrants and income taxes. Actual results could differ from those estimates.

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. The Company has utilized various valuation methodologies in accordance with the framework of the

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Allena Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements (continued)
(information as of June 30, 2017 and for the six months ended June 30, 2017 and 2016 is unaudited)

American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation* (the "Practice Aid"), to estimate the fair value of its common stock. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision-maker, the Company's chief executive officer, views the Company's operations and manages its business as a single operating segment, which is the business of discovering and developing non-absorbed oral enzyme therapeutics.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company's only element of other comprehensive income (loss) is unrealized gains and losses on available-for-sale investments.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Cash and cash equivalents include cash held in banks and amounts held in money market funds. Cash equivalents are stated at cost, which approximates market value.

Cash and cash equivalents consist of the following at December 31, 2015 and 2016 and June 30, 2017 (in thousands):

	December 31,		June 30,
	2015	2016	2017
Cash and cash equivalents:			
Cash	$ 686	$ 948	$ 936
Money market funds	68,325	24,302	33,777
	$69,011	$25,250	$34,713

Investments

The Company invests available cash primarily in U.S. and foreign corporate debt securities and United States government treasury securities. The Company classifies its investments as available-for-sale. Available-for-sale investments are carried at fair value with unrealized gains and losses included in stockholders' (deficit) equity. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expense. All investments are classified as current assets as they have contractual maturities of less than one year and are available to meet working capital needs and to fund current operations.

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The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included in interest income (expense) within the statement of operations and comprehensive loss.

The Company evaluates its investments with unrealized losses for other-than-temporary impairment. When assessing investments for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be "other than temporary", the Company reduces the investment to fair value through a charge to the statement of operations and comprehensive loss. No such adjustments were necessary during the periods presented.

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and investments. The Company maintains all of its cash, cash equivalents and investments balances at a single accredited financial institution, in amounts that exceed federally insured limits. The Company generally invests its excess cash in money market funds, corporate notes and United States government securities that are subject to minimal credit and market risk. Management has established guidelines relative to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. The investment portfolio is maintained in accordance with the Company's investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer.

The Company has no significant off-balance sheet risk such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

Significant Suppliers

The Company is dependent on third-party manufacturers to supply products for research and development activities of its programs, including preclinical and clinical testing. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received upon sale of an asset or paid to transfer a liability between market participants at measurement dates. ASC Topic 820, *Fair Value Measurement* ("ASC 820"), establishes a three-level valuation hierarchy for instruments measured at fair value. The hierarchy is based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The hierarchy defines three levels of valuation inputs, of which the first two are considered observable and the last is considered unobservable:

Level 1 inputs: Quoted prices in active markets for identical assets or liabilities.

Level 2 inputs: Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.

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Level 3 inputs: Unobservable inputs developed using estimates or assumptions developed by the Company, which reflect those that a market participant would use in pricing the asset or liability.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Property and Equipment

Property and equipment consists of laboratory equipment, computer equipment, software and leasehold improvements recorded at cost. These amounts are depreciated using the straight-line method over the estimated useful lives of the assets as follows:

Laboratory equipment	4 years
Computer equipment	3 years
Software	5 years
Leasehold improvements	Shorter of useful life or remaining term of related lease

Upon retirement or sale, the cost of the assets disposed of and the related accumulated depreciation are eliminated from the balance sheet and related gains or losses are reflected in the statement of operations and comprehensive loss.

Repairs and maintenance costs are expensed as incurred and costs of significant improvements are capitalized.

Impairment of Long-Lived Assets

The Company continually evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book values of the assets exceed their fair value. The Company did not recognize any impairment losses for the years ended December 31, 2015 and 2016 and the six months ended June 30, 2016 and 2017.

Warrants to Purchase Shares Subject to Redemption

The Company accounts for warrant instruments that either conditionally or unconditionally obligate the issuer to transfer assets as liabilities regardless of the timing of the redemption feature or price, even though the underlying shares may be classified as equity. These warrants are subject to revaluation at each balance sheet date, and any changes in fair value are recorded as a component of other income (expense) in the statements of operations and comprehensive loss, until the earlier of their exercise or expiration or the completion of a liquidation event, at which time the warrant liability may be reclassified to stockholders' (deficit) equity if the criteria for recording the warrant as an equity instrument are met.

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Research and Development

The Company expenses all costs incurred in performing research and development activities. Research and development expenses include salaries and benefits, materials and supplies, preclinical and clinical trial expenses, manufacturing expenses, stock-based compensation expense, depreciation of equipment, contract services and other outside expenses. Costs of certain development activities, such as manufacturing, are recognized based on an evaluation of the progress to completion of specific tasks. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development costs. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

Patent Costs

The Company expenses patent application and related legal costs as incurred and classifies such costs as general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

Accounting for Stock-Based Compensation

The Company accounts for its stock-based compensation in accordance with ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). ASC 718 requires all share-based payments to employees and directors to be recognized as expense in the statements of operations and comprehensive loss based on their grant date fair values. The Company accounts for share-based payments to non-employees in accordance with ASC Topic 505, *Equity-Based Payments to Non-Employees* ("ASC 505"). Since our non-employee awards do not contain performance commitments, ASC 505 requires that the expense be recognized in the statement of operations and comprehensive loss based on the awards' vesting date fair values. The Company estimates the fair value of options granted using the Black-Scholes option pricing model for stock option grants to both employees and non-employees. The Company believes the fair value of the stock options granted to non-employees is more reliably determinable than the fair value of the services provided.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of a public market for the Company's common stock and a lack of company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. For options granted to non-employees, the Company utilizes the contractual term of the share-based payment as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

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There are significant judgments and estimates inherent in the determination of the fair value of the Company's common stock. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to its common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale.

The Company prepared a common stock valuation as of November 6, 2014 which supported the fair value of the Company's common stock for certain awards in the year ended December 31, 2015 using the backsolve method to calculate the total equity value and the option-pricing method ("OPM") to allocate the total equity value. The backsolve method derives the implied equity value for one type of equity security from a contemporaneous transaction involving another type of security to calculate the equity value. The Company's subsequent common stock valuations were prepared using the backsolve method to calculate the total equity value and a hybrid of the OPM and probability-weighted expected return method ("PWERM"), including a future IPO scenario, to allocate the total equity value.

In the first quarter of 2017, the Company made an accounting policy election to recognize forfeitures as they occur upon adoption of guidance per ASU No. 2016-09, *Compensation—Stock Compensation*. The adoption of ASU No. 2016-09 did not have a material impact on the Company's financial statements. In reporting periods prior to 2017, the Company estimated forfeitures at the time of grant and revised the forfeitures rate in subsequent periods as necessary if actual forfeitures differed from estimates.

Through December 31, 2016, the Company was required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differed from its estimates. The Company used historical data to estimate pre-vesting forfeitures and recorded stock-based compensation expense only for those awards that were expected to vest. To the extent that actual forfeitures differed from estimates, the difference was recorded as a cumulative adjustment in the period the estimates were revised.

The Company expenses the fair value of its share-based compensation awards to employees on a straight-line basis over the requisite service period, which is generally the vesting period. Stock-based compensation awards to non-employees are adjusted through stock-based compensation expense at each reporting period end to reflect the current fair value of such awards and are expensed on a straight-line basis.

Income Taxes

The Company accounts for income taxes using the liability method in accordance with ASC Topic 740, *Income Taxes* ("ASC 740"). The difference between the financial statement and tax basis of the assets and liabilities is determined annually. Deferred income tax assets and liabilities are computed using the tax laws and rates that are expected to apply for periods in which such differences reverse. Valuation allowances are established, if necessary, to reduce the deferred tax asset to the amount that will more likely than not be realized.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs.

Net Loss per Share

The Company has reported losses since inception and has computed basic net loss per share attributable to common stockholders by dividing net loss attributable to common stockholders by the weighted-average number

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of common shares outstanding for the period, without consideration for potentially dilutive securities. The Company has computed diluted net loss per common share after giving consideration to all potentially dilutive common shares, including options to purchase common stock, restricted common stock, convertible preferred stock and warrants to purchase convertible preferred stock, outstanding during the period determined using the treasury-stock and if-converted methods, except where the effect of including such securities would be antidilutive. Because the Company has reported net losses since inception, these potential common shares have been anti-dilutive and basic and diluted loss per share have been the same.

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share data):

	Years Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
Numerator:				
Net loss	$ (14,247)	$ (24,507)	$ (12,152)	$ (10,303)
Accretion of convertible preferred stock	(37)	(69)	(34)	(34)
Net loss attributable to common stockholders	$ (14,284)	$ (24,576)	$ (12,186)	$ (10,337)
Denominator:				
Weighted-average common shares—basic and diluted	1,258,123	1,339,254	1,337,100	1,342,628
Net loss per share attributable to common stockholders—basic and diluted	$ (11.35)	$ (18.35)	$ (9.11)	$ (7.70)

The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to include them would be anti-dilutive (in common stock equivalent shares):

	Years Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
Series A convertible preferred stock	4,400,410	4,400,410	4,400,410	4,400,410
Series B convertible preferred stock	4,753,536	4,753,536	4,753,536	4,753,536
Series C convertible preferred stock	4,791,563	4,791,563	4,791,563	4,791,563
Warrants	34,225	43,265	41,005	43,265
Stock options	759,167	1,348,845	1,120,881	1,394,299
Restricted stock	675	—	—	—
Total	14,739,576	15,337,619	15,107,395	15,383,073

Pro Forma Net Loss per Share

Unaudited pro forma net loss per share attributable to common stockholders is computed using the weighted-average number of common shares outstanding after giving effect to the conversion of all the convertible preferred stock into shares of common stock as if such conversion had occurred at the beginning of the period presented or the date of original issuance, if later.

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The following table summarizes the Company's unaudited pro forma net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Year Ended December 31, 2016	Six Months Ended June 30, 2017
Numerator:		
Net loss attributable to common stockholders	$ (24,507)	$ (10,303)
Accretion of convertible preferred stock	69	34
Change in fair value of warrant liability	132	32
Pro forma net loss attributable to common stockholders	$ (24,306)	$ (10,237)
Denominator:		
Weighted-average common shares outstanding—basic and diluted	1,339,254	1,342,628
Adjustment for assumed conversion of convertible preferred stock	13,945,509	13,945,509
Pro forma weighted-average common shares outstanding—basic and diluted	15,284,763	15,288,137
Pro forma net loss per share attributable to common stockholders—basic and diluted	$ (1.59)	$ (0.67)

Loss Contingencies

In accordance with ASC 450, *Contingencies*, the Company accrues anticipated costs of settlement, damages, and losses for loss contingencies based on historical experience or to the extent specific losses are probable and estimable. Otherwise, the Company expenses these costs as incurred. If the estimate of a probable loss is a range, and no amount within the range is more likely, the Company accrues the minimum amount of the range.

Guarantees

The Company has identified the guarantees described below as disclosable, in accordance with ASC 460, *Guarantees*.

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that should limit its exposure and enable it to recover a portion of any future amounts paid.

The Company is a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate the Company to indemnify the other parties to such agreements upon the occurrence of certain events. Such indemnification obligations are usually in effect from the date of execution of the applicable agreement for a period equal to the applicable statute of limitations. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain.

The Company leases office space under several noncancelable operating leases. The Company has standard indemnification arrangements under these leases that require it to indemnify the landlord against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation, or nonperformance of any covenant or condition of the respective lease.

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As of December 31, 2015 and 2016 and June 30, 2017, the Company had not experienced any losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves have been established.

Deferred Initial Public Offering Costs

The Company capitalizes deferred initial public offering ("IPO") costs, which primarily consist of direct, incremental legal, professional, accounting and other third-party fees relating to the Company's initial public offering, within other non-current assets. The deferred IPO costs will be offset against IPO proceeds upon the consummation of an offering. There were no deferred IPO costs as of December 31, 2016 and approximately $114,000 of deferred IPO costs were incurred and capitalized as of June 30, 2017.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its consolidated financial position or results of operations upon adoption.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern* ("ASU No. 2014-15"), which defines management's responsibility to evaluate, at each annual and interim reporting period, whether there are conditions or events that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date the financial statements are issued and to provide related footnote disclosures in certain circumstances. In connection with each annual and interim period, management must assess if there is substantial doubt about the company's ability to continue as a going concern within one year after the issuance date. Disclosures are required if conditions give rise to substantial doubt. This standard is effective for all companies in the first annual period ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The Company adopted ASU No. 2014-15 for the year ended December 31, 2016. The adoption of ASU No. 2014-15 did not have a significant impact on the Company's financial statement disclosures. Refer to Note 1 for a discussion of the Company's liquidity.

In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs*. This standard amends existing guidance to require the presentation of debt issuance costs in the balance sheet as a deduction from the carrying amount of the related debt liability rather than as a deferred charge. It is effective for annual reporting periods beginning after December 15, 2015. The Company adopted the standard on January 1, 2016 and reclassified its debt issuance costs to a reduction of the debt balances, accordingly. The adoption did not have a material impact on the Company's consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* ("ASU No. 2015-17"), which simplifies the presentation of deferred income taxes by eliminating the need for entities to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. For non-public entities, the guidance in this ASU is effective for annual periods beginning after December 15, 2017 and interim periods within annual periods beginning after December 15, 2018. Earlier application is permitted for all entities as of the beginning of an interim or an annual reporting period. The Company prospectively adopted this ASU as of January 1, 2017. Prior period amounts were not retrospectively adjusted, and the adoption of ASU No. 2015-17 did not have a material impact on the Company's consolidated balance sheets.

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In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU No. 2016-02"). The new standard aims to increase transparency and comparability among organizations by requiring lessees to recognize lease assets and lease liabilities on the balance sheet and requiring disclosure of key information about leasing arrangements. ASU No. 2016-02 is effective for public entities for annual periods beginning after December 15, 2018 and for interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the potential impact that ASU No. 2016-02 may have on its financial position and results of operations.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation-Stock Compensation* ("ASU No. 2016-09"), which amends ASC Topic 718, *Compensation-Stock Compensation.* ASU No. 2016-09 identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. The amendments are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The Company adopted ASU No. 2016-09 effective January 1, 2017. The adoption of ASU No. 2016-09 did not have a material impact on the Company's financial statements. Upon adoption, the Company elected to account for forfeitures as they occur. The Company did not have any excess tax benefits associated with stock option exercises and therefore there was no deferred tax asset recorded upon adoption.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* ("ASU No. 2016-15"). This guidance addresses the presentation and classification of certain cash receipts and cash payments in the statement of cash flows. The standard is effective for annual periods beginning after December 15, 2017 and for interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the potential impact that the adoption of ASU No. 2016-15 will have on its financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU No. 2017-09"). This update clarifies the changes to terms or conditions of a share-based payment award that require an entity to apply modification accounting. ASU No. 2017-09 is effective for annual reporting periods, and interim periods therein, beginning after December 15, 2017. Early application is permitted and prospective application is required. The Company does not expect that the adoption of this guidance will have a significant impact on the Company's financial position, results of operations or cash flows.

3. Investments

The Company did not have any investments as of December 31, 2015.

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The following table summarizes the Company's investments as of December 31, 2016 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Available-for-sale securities:				
U.S. treasury securities	$ 13,258	$ 3	$ (2)	$ 13,259
U.S. corporate debt securities	7,397	—	(3)	7,394
Foreign corporate debt securities	2,852	—	—	2,852
Total available-for-sale securities	$ 23,507	$ 3	$ (5)	$ 23,505

The aggregate fair value of investments with unrealized losses was approximately $16.5 million at December 31, 2016. At December 31, 2016, 10 investments were in an unrealized loss position. All such investments have been in an unrealized loss position for less than a year and these losses are considered temporary. The Company has the ability and intent to hold these investments until a recovery of their amortized cost.

The following table summarizes the Company's investments as of June 30, 2017 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Available-for-sale securities:				
U.S. treasury securities	$ 3,249	$ —	$ —	$ 3,249
Total available-for-sale securities	$ 3,249	$ —	$ —	$ 3,249

4. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities that have been measured at fair value at December 31, 2015 and 2016 and June 30, 2017 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

Description	December 31, 2015	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds, included in cash and cash equivalents	$ 68,325	$68,325	$ —	$ —
Total assets	$ 68,325	$68,325	$ —	$ —
Liabilities:				
Warrants for the purchase of shares subject to redemption	$ 68	$ —	$ —	$ 68
Total liabilities	$ 68	$ —	$ —	$ 68

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Description	December 31, 2016	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds, included in cash and cash equivalents	$ 24,302	$24,302	$ —	$ —
Investments:				
U.S. treasury securities	13,259	13,259	—	—
U.S. corporate debt securities	7,394	—	7,394	—
Foreign corporate debt securities	2,852	—	2,852	—
Total assets	$ 47,807	$37,561	$ 10,246	$ —
Liabilities:				
Warrants for the purchase of shares subject to redemption	$ 267	$ —	$ —	$ 267
Total liabilities	$ 267	$ —	$ —	$ 267

Description	June 30, 2017	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds, included in cash and cash equivalents	$33,777	$33,777	$ —	$ —
Investments:				
U.S. treasury securities	3,249	3,249	—	—
Total assets	$37,026	$37,026	$ —	—
Liabilities:				
Warrants for the purchase of shares subject to redemption	$ 299	$ —	$ —	$ 299
Total liabilities	$ 299	$ —	$ —	$ 299

At December 31, 2015 and 2016 and June 30, 2017, all of the Company's cash equivalents were comprised of money market funds.

At December 31, 2016 and June 30, 2017, items classified as Level 2 within the valuation hierarchy consist of U.S. and foreign corporate debt securities. The Company estimates the fair values of these investments by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include market pricing based on real-time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs. The Company validates the prices provided by its third-party pricing sources by understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances.

At December 31, 2015 and 2016 and June 30, 2017, the Company's warrants for the purchase of shares subject to redemption were the only financial instruments classified as Level 3.

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There have been no changes to the valuation methods used during the years ended December 31, 2015 and 2016 and the six months ended June 30, 2017. There were no transfers within the fair value hierarchy during the years ended December 31, 2015 and 2016 and the six months ended June 30, 2017.

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their carrying values. The Company believes the terms of the loan payable reflect current market conditions for an instrument with similar terms and maturity, therefore the carrying value of the Company's debt approximates its fair value based on Level 3 of the fair value hierarchy.

Warrants to Purchase Shares Subject to Redemption

In connection with entering into a Loan and Security Agreement ("Loan Agreement") in August 2014 (Note 7), the Company issued a warrant for the purchase of 71,428 shares of Series A preferred stock ("Series A Warrant") when the Loan Agreement was executed. In connection with the first advance under the Loan Agreement, the Series A Warrant became exercisable for an additional 38,265 shares. In connection with a second advance under the Loan Agreement in March 2015, the Series A Warrant became exercisable for an additional 33,163 shares. The Company amended the Loan Agreement in May 2016. In connection with the first advance under the amended Loan Agreement in May 2016, the Company issued a warrant for the purchase of up to 28,302 shares of Series C preferred stock ("Series C Warrant", together with the Series A Warrant, the "Warrants"). In connection with the second advance under the amended Loan Agreement in December 2016, the Series C Warrant became exercisable for an additional 9,434 shares. The estimated fair value of the Warrants was determined using the Black- Scholes option-pricing model. A significant input to the fair value of the warrants is the fair value of the Series A Preferred Stock and the C Preferred Stock which was determined based upon the Company's common stock valuations. The fair value of the Warrants is remeasured at each reporting date using then-current assumptions with changes in fair value charged to other income (expense) on the statements of operations and comprehensive loss. As of December 31, 2015 and 2016 and June 30, 2017, the Warrants were valued at $68,000, $0.3 million and $0.3 million, respectively. The following assumptions were used in valuing the Warrants:

	Original Issuance Date			
	August 18, 2014	March 30, 2015	May 2, 2016	December 28, 2016
Risk-free interest rate	2.4%	2.0%	1.9%	2.5%
Estimated fair value of underlying shares	$ 0.98	$ 0.31	$1.92	$ 2.73
Expected dividend yield	—%	—%	—%	—%
Expected term (in years)	10.0	9.4	10.0	9.4
Expected volatility	80%	88%	90%	90%

	December 31,		
	2015	2016	June 30, 2017
Risk-free interest rate	2.2%	2.3%-2.5%	2.1%-2.2%
Expected dividend yield	—%	—%	—%
Expected term (in years)	8.6	7.6-9.3	7.1-8.9
Expected volatility	85%	90%	87%-91%

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The following table sets forth a summary of changes in the fair value of the Warrants, which represented a recurring measurement classified within Level 3 of the fair value hierarchy, wherein fair value was estimated using significant unobservable inputs (in thousands, except share data):

Balance at December 31, 2014	$ 25
Initial fair value of Series A Warrant for the purchase of 33,163 shares	7
Change in fair value of Series A Warrant included in other income (expense)	36
Balance at December 31, 2015	68
Initial fair value of Series C Warrant for the purchase of 28,302 shares	45
Initial fair value of Series C Warrant for the purchase of 9,434 shares	22
Change in fair value of Warrants included in other income (expense)	132
Balance at December 31, 2016	267
Change in fair value of Warrants included in other income (expense)	32
Balance at June 30, 2017	$299

An entity may choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. The Company did not elect to measure any financial instruments or other items at fair value.

5. Property and Equipment, Net

Property and equipment includes the following at December 31, 2015 and 2016 and June 30, 2017 (in thousands):

	December 31,		June 30,
	2015	2016	2017
Property and equipment:			
Laboratory equipment	$ 165	$ 232	$ 251
Computer equipment	—	6	6
Software	—	39	39
Leasehold improvements	109	—	—
	274	277	296
Less: Accumulated depreciation	(185)	(108)	(143)
Property and equipment, net	$ 89	$ 169	$ 153

The Company recognized $0.1 million, $46,000, $21,000 and $34,000 of depreciation expense for the years ended December 31, 2015 and 2016 and the six months ended June 30, 2016 and 2017, respectively.

In September 2016, the Company wrote-off $0.1 million of fully depreciated leasehold improvements upon moving out of a laboratory facility.

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6. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,		June 30,
	2015	2016	2017
Payroll and employee-related expenses	$534	$ 914	$ 566
Professional fees	179	172	138
Third-party research and development expenses	149	413	93
Loan interest	18	28	38
Other	47	83	11
Total accrued expenses	$927	$1,610	$ 846

7. Loan and Security Agreement

In August 2014, the Company entered into a Loan Agreement with Silicon Valley Bank ("SVB") to borrow up to $7.0 million. Upon entering into the Loan Agreement, SVB advanced $3.8 million to the Company. In March 2015, SVB advanced the remaining $3.2 million available under the Loan Agreement.

In May 2016, the Loan Agreement was amended ("Amended Loan Agreement") to borrow up to $10.0 million with a portion of the proceeds to be used to pay down the outstanding balance of the original $7.0 million of advances. At the time of the Amended Loan Agreement, SVB advanced a gross amount of $7.5 million to the Company. Net proceeds received by the Company were $1.6 million after deducting $5.3 million for repayment of the original advances and $0.6 million for final interest due upon maturity or prepayment of the original advances. The Amended Loan Agreement was accounted for as a debt modification pursuant to ASC 450-70, *Modifications or Extinguishments*. In December 2016, upon the achievement of certain milestones, SVB advanced the remaining $2.5 million available under the Amended Loan Agreement.

The borrowings are secured by a lien on all Company assets, excluding intellectual property. The May 2016 and December 2016 advances have a floating per annum interest rate of the greater of 4.0% or 0.5% above the prime rate. The interest rate on the borrowings at December 31, 2016 and June 30, 2017 was 4.25% and 4.75%, respectively. Beginning in May 2016, payments were interest only for a period of 12 months. In December 2016, the interest only period was extended to 18 months. Upon the expiration of the interest only period, amounts borrowed will be repaid over 30 equal monthly payments of principal and interest. At its option, the Company may prepay all, but not less than all, of the outstanding borrowings subject to a prepayment premium as defined in the Amended Loan Agreement. The Company is also required to make a final payment equal to 8.25% of the total borrowings which is due on the earliest of the loan maturity date, an acceleration of the loan as defined in the Amended Loan Agreement or at the time of prepayment. The final payment is being accreted to interest expense through the maturity date of the loan.

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The minimum aggregate future loan and interest payments at December 31, 2016 are as follows (in thousands):

Years Ending December 31,	
2017	$ 742
2018	4,223
2019	4,223
2020	2,585
Total minimum payments	11,773
Less: Amount representing interest	(1,773)
Less: Discount	(415)
Less: Current portion	(176)
Loan payable, net of current portion	$ 9,409

The Company issued the Series A Warrant to SVB to purchase 71,428 shares of Series A convertible preferred stock ("Series A Preferred Stock") at $0.98 per share upon executing the Loan Agreement. In addition, the Company issued an additional Warrant to SVB to purchase a number of shares of Series A Preferred Stock equal to 1.0% of each additional loan advance amount. In connection with the initial advance and the advance in March 2015, the Series A Warrant became exercisable for an additional 38,265 and 33,163 shares of Series A Preferred Stock at $0.98 per share, respectively. The Series A Warrant expires on August 17, 2024. Under the terms of the Amended Loan Agreement, the Company issued a Series C Warrant to SVB to purchase a number of shares of Series C convertible preferred stock ("Series C Preferred Stock") at $2.65 per share equal to 1.0% of each loan advance amount. In connection with the initial advance and the advance in December 2016, the Series C Warrant became exercisable for 28,302 and 9,434 shares of Series C Preferred Stock at $2.65 per share, respectively. The Series C Warrant expires on May 1, 2026.

The Company recorded the fair value of the Warrants at issuance as a reduction to the loan payable balance. The discount is being accreted to interest expense over the period that the loan will be outstanding. The offsetting credit was recorded as warrants to purchase shares subject to redemption in the long-term liabilities section on the consolidated balance sheets. The fair value of the Warrants is remeasured at each reporting period and changes in fair value are recognized in other income (expense) in the statement of operations.

The Amended Loan Agreement contains negative covenants restricting the Company's activities, including limitations on dispositions, mergers or acquisitions, incurring indebtedness or liens, paying dividends or making investments and certain other business transactions. There are no financial covenants associated with the Amended Loan Agreement. The obligations under the Amended Loan Agreement are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in the Company's business, operations or financial or other condition. The Company has determined that the risk of subjective acceleration under the material adverse events clause is remote and therefore has classified the outstanding principal in current and long-term liabilities based on scheduled principal payments.

The Loan Agreement was previously amended in December 2014 in conjunction with the formation of the Security Corporation, requiring the Company to maintain a balance of cash and cash equivalents in the Company's operating, depository and securities accounts in an amount not less than 125% of the outstanding debt balance so long as the Company maintains a cash balance in the Security Corporation. At December 31, 2015 and 2016 and June 30, 2017, the Company was required to have and had a balance of not less than $7.8 million, $12.5 million and $12.5 million, respectively, included in cash and cash equivalents, representing

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125% of the outstanding debt balances at December 31, 2015 and 2016 and June 30, 2017 of $6.3 million, $10.0 million and $10.0 million, respectively, in the Company's operating account.

The Company evaluated the Loan Agreement and Amended Loan Agreement for embedded features that require bifurcation, noting that the contingent interest feature and the incremental interest upon an event of default were required to be bifurcated, but were concluded to be de minimus in value at inception and at December 31, 2015 and 2016 and June 30, 2017.

8. Convertible Preferred Stock

Series A Convertible Preferred Stock

From September 2011 to May 2014, the Company issued a total of 18,367,344 shares of Series A Preferred Stock at $0.98 per share for total net proceeds of $17.9 million.

Series B Convertible Preferred Stock

In November 2014, the Company issued 19,841,270 shares of the Series B Convertible Preferred Stock ("Series B Preferred Stock") at $1.26 per share for net proceeds of $24.9 million.

Series C Convertible Preferred Stock

In November 2015, the Company issued 20,000,000 shares of the Series C Preferred Stock (collectively with the Series A Preferred Stock and Series B Preferred Stock, the "Preferred Stock") at $2.65 per share for net proceeds of $52.8 million.

The Preferred Stock has the following rights and preferences:

Conversion

The Preferred Stock is convertible into common stock at any time at the option of the holder, initially on a 1-for-0.2396 basis, and is subject to mandatory conversion upon (1) the closing of a firm commitment underwritten public offering with proceeds of at least $50.0 million or (2) upon the written notice from the holders of at least 60% of the then-outstanding shares of Preferred Stock, voting together as a single class on an as converted basis and at least a majority of the then outstanding shares of the Series C Preferred Stock, voting as a separate class, at the original issue price per share plus any declared but unpaid dividends.

Voting

The holders of the Preferred Stock have voting rights equivalent to the number of shares of common stock into which their shares convert.

Dividends

Holders of Series C Preferred Stock are entitled to receive, before any cash is paid out or set aside for any other class or series of capital stock, dividends at 8% of the Series C Preferred Stock issuance price, subject to adjustment for any stock dividend, stock split, or other similar recapitalization affecting such class or series of capital stock. The dividends are non-cumulative, and are payable only when and if declared by the Board of Directors of the Company.

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Holders of shares of Series A Preferred Stock and Series B Preferred Stock are then entitled to receive, before or simultaneously with common stockholders, a dividend at least equal to the amount of dividends per share received by the common stockholders. No dividends have been declared since the Company's inception.

Liquidation Preference

Upon a voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of the Series A, Series B and Series C Preferred Stock are entitled to receive an amount equal to $0.98 per share, $1.26 per share and $2.65 per share, respectively, plus declared but unpaid dividends. Holders of Series C Preferred Stock are entitled to receive payment prior to holders of Series B Preferred Stock, and holders of Series B Preferred Stock prior to holders of Series A Preferred Stock. After the payment of all preferential amounts required to be paid upon liquidation to the holders of the Preferred Stock, holders of the Preferred Stock will also share in the remaining assets with holders of the common stock on a pro-rata basis, assuming conversion into common stock. However, the aggregate amount paid to the holders of Series A, Series B and Series C Preferred Stock shall not exceed the greater of $1.96 per share, $2.52 per share and $5.30 per share, respectively, and the amount such holder would have received if all shares of Series A, Series B and Series C Preferred Stock had been converted into common stock immediately prior to liquidation. If the assets available for distribution are insufficient to pay the holders the full amount to which they are entitled, the holders of Series C Preferred Stock (and subsequently the holders of Series B and Series A Preferred Stock, as applicable) will share ratably in any distribution of the assets available in proportion to the amounts that would otherwise be payable.

Redemption

The Company shall redeem the outstanding shares of Preferred Stock in three annual installments at any time on or after November 25, 2020 upon the written notice from the holders of at least 60% of the then-outstanding shares of Preferred Stock, voting together as a single class on an as converted basis and at least a majority of the then outstanding shares of Series C Preferred Stock, voting as a separate class, at the original issue price per share plus any declared but unpaid dividends.

The Company's Preferred Stock has been classified as temporary equity on the accompanying consolidated balance sheets in accordance with authoritative guidance for the classification and measurement of redeemable securities as the Preferred Stock is redeemable at a determinable price on a fixed date or upon the occurrence of a deemed liquidation event. The Preferred Stock is being accreted to its redemption value through the earliest redemption date.

9. Stockholders' (Deficit) Equity

Common Stock

The holders of common stock are entitled to one vote for each share held. Common stockholders are not entitled to receive dividends, unless declared by the Board of Directors.

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The Company has reserved for future issuances the following shares of common stock as of December 31, 2016 and June 30, 2017:

	As of December 31, 2016	As of June 30, 2017
Series A convertible preferred stock	4,400,410	4,400,410
Series B convertible preferred stock	4,753,536	4,753,536
Series C convertible preferred stock	4,791,563	4,791,563
Warrants	43,265	43,265
Stock options	2,130,560	2,128,938
Total	16,119,334	16,117,712

Restricted Common Stock

In 2011 and 2012, the Company issued a total of 1,211,035 shares of restricted common stock to founders, employees, directors and consultants. These shares of common stock vested over four years. If any of these individuals ceased to be employed or to provide services to the Company prior to vesting, the Company had the right to repurchase any unvested shares of common stock at the price paid by the holder.

A summary of the status of unvested restricted common stock as of December 31, 2015 and 2016 is presented below:

	Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2014	163,568	$ 0.42
Granted	—	—
Vested	(162,893)	0.42
Cancelled	—	—
Unvested at December 31, 2015	675	0.42
Granted	—	—
Vested	(675)	0.42
Cancelled	—	—
Unvested at December 31, 2016	—	$ —

There was no unvested restricted common stock outstanding at June 30, 2017.

The fair value of restricted stock awards that vested during the years ended December 31, 2015 and 2016, based on estimated fair values of the stock underlying the restricted stock awards on the day of vesting, was $190,400 and $800, respectively.

10. Stock Incentive Plan

In September 2011, the Company adopted the 2011 Stock Incentive Plan ("2011 Plan"). All of the Company's employees, officers, directors, consultants and advisors are eligible to be granted options, restricted

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stock units ("RSUs"), and other share-based awards under the terms of the 2011 Plan. The 2011 Plan provides for the grant of awards for 2,293,272 shares of common stock. As of December 31, 2016 and June 30, 2017, 778,074 and 734,590 shares of common stock were available for future grant under the 2011 Plan, respectively.

All stock option grants are nonstatutory stock options except option grants to employees (including officers and directors) intended to qualify as incentive stock options under the Internal Revenue Code of 1986, as amended. Incentive stock options may not be granted at less than the fair market value of the Company's common stock on the date of grant, as determined in good faith by the Board of Directors at its sole discretion. Nonqualified stock options may be granted at an exercise price established by the Board of Directors at its sole discretion (which has not been less than fair market value on the date of grant) and the vesting periods may vary. Vesting periods are generally four years and are determined by the Board of Directors or a delegated subcommittee. Stock options become exercisable as they vest. Options granted under the 2011 Plan expire no more than 10 years from the date of grant.

Stock-based compensation expense included in the Company's statements of operations and comprehensive loss is as follows (in thousands):

	Years Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
Research and development	$ 74	$ 68	$ 28	$ 57
General and administrative	133	183	71	139
Total	$ 207	$ 251	$ 99	$ 196

The fair value of each stock option granted to employees and directors was estimated on the date of grant using the Black-Scholes option-pricing model, with the following range of assumptions for the years ended December 31, 2015 and 2016, and the six months ended June 30, 2016 and 2017:

	Years Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
Risk-free interest rate	1.8%-1.9%	1.3%-1.7%	1.4%-1.7%	1.9%-2.0%
Expected dividend yield	—%	—%	—%	—%
Expected term (in years)	6.25	5.4-6.4	5.4-6.5	5.6-6.3
Expected volatility	85%	77%-84%	83%-84%	84%-87%

The expense related to awards granted to employees and directors for their service on the Board of Directors was $179,000, $227,000, $89,000 and $169,000 for the years ended December 31, 2015 and 2016 and for the six months ended June 30, 2016 and 2017, respectively.

The fair value of each stock option granted to non-employees was estimated on the date of grant using the Black-Scholes option-pricing model, with the following range of assumptions for the years ended December 31, 2015 and 2016, and the six months ended June 30, 2016 and 2017:

	Years Ended December 31,		Six Months Ended June 30,
	2015	2016	2016
Risk-free interest rate	2.4%	1.9%-2.4%	1.9%-2.4%
Expected dividend yield	—%	—%	—%
Expected term (in years)	10.0	8.9-10.0	8.9-10.0
Expected volatility	85%	89%-96%	89%-96%

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We did not grant any stock options to non-employees during the six months ended June 30, 2017. The expense related to awards granted to non-employees was $28,000, $24,000, $10,000 and $27,000 for the years ended December 31, 2015 and 2016 and for the six months ended June 30, 2016 and 2017, respectively.

A summary of the stock option activity under the 2011 Plan is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2015	759,167	$ 1.04	8.8	$ 399
Granted	620,137	1.59		
Exercised	(24,770)	0.75		
Cancelled	(5,689)	1.34		
Outstanding at December 31, 2016	1,348,845	1.29	8.6	$ 3,642
Granted	51,067	4.01		
Exercised	(1,621)	1.46		
Cancelled	(3,992)	1.46		
Outstanding at June 30, 2017	1,394,299	$ 1.41	8.1	$ 4,850
Exercisable at December 31, 2016	455,417	$ 1.13	7.9	$ 1,318
Vested and expected to vest at December 31, 2016	1,348,845	$ 1.29	8.6	$ 3,642
Exercisable at June 30, 2017	653,187	$ 1.21	7.7	$ 2,411
Vested and expected to vest at June 30, 2017	1,394,299	$ 1.41	8.1	$ 4,850

The weighted-average fair value of options granted to employees and directors for their service on the Board of Directors during the years ended December 31, 2015 and 2016 and six months ended June 30, 2016 and 2017 was $0.83, $1.13, $1.13 and $2.92 per share, respectively. The weighted-average fair value of options granted to non-employees during the years ended December 31, 2015 and 2016 and six months ended June 30, 2016 was $1.00, $1.38 and $1.38 per share, respectively. There were no options granted to non-employees during the six months ended June 30, 2017.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The total intrinsic value of options exercised during the years ended December 31, 2015 and 2016 and the six months ended June 30, 2016 and 2017 was $2,000, $21,000, $21,000 and $4,000, respectively.

As of December 31, 2016 and June 30, 2017, total unrecognized stock-based compensation expense relating to unvested stock options was $0.8 million and $0.9 million, respectively. This amount is expected to be recognized over a weighted-average period of 2.4 years.

11. Income Taxes

The Company has incurred net operating losses ("NOLs") from inception. At December 31, 2016, the Company has NOL carryforwards of approximately $58.8 million available to reduce future taxable income,

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which expire beginning in 2031. The Company also has federal research and development tax credit carryforwards of approximately $2.4 million available to reduce future tax liabilities and which expire beginning in 2031. The Company has state NOL carryforwards of approximately $57.5 million available to reduce state future taxable income, which will expire beginning in 2031. The Company also has state research and development tax credit carryforwards of $1.6 million available to reduce future tax liabilities and which will expire beginning in 2026.

The Company does not have any NOL carryforwards associated with deductible stock option exercises as of December 31, 2016.

Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not determined whether an ownership change has occurred and as such, the Company's NOLs may be limited.

A reconciliation of income taxes computed using the U.S. federal statutory rate to that reflected in operations as of December 31, 2015 and 2016 are as follows:

	2015	2016
Income tax computed at federal statutory tax rate	34.0%	34.0%
Permanent differences	(0.4)%	(0.5)%
State taxes, net of federal benefit	(0.1)%	5.1%
Research and development tax credits	5.5%	6.1%
Other	0.1%	0.0%
Change in deferred tax asset valuation allowance	(39.1)%	(44.7)%
	0.0%	0.0%

The Company's deferred tax assets at December 31, 2016 and 2015, consist of the following (in thousands):

	Years Ended December 31,	
	2015	2016
Deferred tax assets:		
Net operating loss carryforwards	$ 13,592	$ 23,028
Research and development credits	1,922	3,418
Licenses	42	38
Other	63	118
Total gross deferred tax asset	15,619	26,602
Less: Valuation allowance	(15,619)	(26,602)
Net deferred tax asset	$ —	$ —

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

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After consideration of all the evidence, both positive and negative, the Company has recorded a valuation allowance against its deferred tax assets at December 31, 2015 and 2016, respectively, because the Company's management has determined that it is more likely than not that the Company will not recognize the benefits of its federal and state deferred tax assets primarily due to its cumulative loss position and, as a result, a valuation allowance of approximately $15.6 million and $26.6 million has been established at December 31, 2015 and 2016, respectively. The valuation allowance increased by $6.3 million and $11.0 million in the years ended December 31, 2015 and 2016, respectively. The increase in the valuation allowance in 2016 primarily relates to the net loss incurred by the Company.

The Company has no unrecognized tax benefits. The Company has not, as yet, conducted a study of its research and development credit carryforwards. This study may result in an adjustment to the Company's research and development credit carryforwards, however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment were required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations if an adjustment were required.

Interest and penalty charges, if any, related to unrecognized tax benefits would be classified as income tax expense in the accompanying statement of operations. As of December 31, 2015 and 2016, the Company had no accrued interest related to uncertain tax positions. The Company's uncertain tax positions are related to years that remain subject to examination by relevant tax authorities. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available.

12. Related Party Transactions

From September 2015 to June 2017, the Company received consulting and management services from one of its investors, Third Rock Ventures LLP ("Third Rock Ventures"). The Company paid Third Rock Ventures $19,000, $69,000 and $2,000 for these services during the years ended December 31, 2015 and 2016, and the six months ended June 30, 2017, respectively. At December 31, 2015, $33,000 was due to Third Rock Ventures for these services. No amounts were payable to Third Rock Ventures at December 31, 2016 and June 30, 2017.

13. Commitments and Contingencies

In August 2011 and October 2013, the Company and an independent third party entered into operating leases for approximately 6,055 square feet of office space in Newton, MA ("Newton Lease") and approximately 3,170 square feet of laboratory space in Natick, MA, respectively. Base rent for the office space during the initial rent period was approximately $0.1 million per year and increased annually. Base rent for the lab space was approximately $59,000 annually. Rent expense, inclusive of the escalating rent payments and free rent period, was recognized on a straight-line basis over the term of each lease agreement. The Company and the independent third party were each jointly and severally liable for the obligations under both leases. In October 2016, the Newton lease was amended to extend the term one year to May 2018 and, effective June 1, 2017 removed the independent third party from the lease and all related obligations of the lease.

In March 2015, the Company and the independent third party entered into a sublease agreement for approximately 5,385 square feet of office space in Newton, MA that expired in February 2017.

In August 2016, the Company entered into an operating lease for approximately 7,162 square feet of laboratory space in Sudbury, MA. This lease was to expire in August 2017. In February 2017, the Company

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amended this lease to extend the term to February 2019 and reduce the amount of rentable space to approximately 5,133 square feet, with an option to lease the other 2,029 square feet. Base rent for this space is approximately $0.1 million annually.

Rent expense includes the Company's allocated portion of rental obligations under the leases. The Company recorded $0.2 million, $0.2 million, $0.1 million and $0.2 million, of rent expense for the years ended December 31, 2015 and 2016 and the six months ended June 30, 2016 and 2017, respectively.

The minimum aggregate future operating lease commitments at December 31 2016 and June 30, 2017 are as follows (in thousands):

	Total Minimum Lease Payments	
	December 31, 2016	June 30, 2017
2017	$ 370	$ 188
2018	111	253
2019	—	24
	$ 481	$ 465

14. License Agreement

In March 2012, the Company entered into an exclusive license agreement with Althea Technologies, Inc. (now known as Ajinomoto Althea, Inc.) ("Althea"), as amended in March 2016, for certain intellectual property ("License Agreement"). The Company reimbursed Althea for patent related costs incurred by Althea totaling $0.1 million in the aggregate and issued a total of 88,186 shares of common stock to Althea. Under the terms of the License Agreement, the Company is obligated to pay milestone payments and mid-single digit royalties on net sales. Milestone payments are triggered upon the achievement of specified regulatory milestones totaling up to $31.0 million and sales-based milestones up to $25.0 million. The milestone payments are not creditable against royalties. Actual amounts due under the License Agreement will vary depending on the number of products developed, the type and development path of the products, and other related factors. The Company may terminate the agreement at any time with 60 days prior written notice.

15. Employee Benefit Plan

Effective January 2012, employees of the Company are eligible to participate in the Company's 401(k) retirement plan ("401(k) Plan"). Participants may contribute up to 100% of their annual compensation to the 401(k) Plan, subject to statutory limitations. The 401 (k) Plan does not allow the Company to make matching contributions.

16. Subsequent Events

The Company's Board of Directors and stockholders approved a 1-for-4.174 reverse stock split of the Company's common stock that became effective on October 23, 2017. All share and per share amounts in the consolidated financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse split.

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5,333,333 Shares

Common Stock

Prospectus
November 1, 2017

Through and including November 26, 2017 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.